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Timm et al.

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(54) **DYNAMIC SPINE STABILIZATION DEVICE WITH TRAVEL-LIMITING FUNCTIONALITY**

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AU 744241 7/1999

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 772 days.

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(21) Appl. No.: **11/189,512**

Panjabi, The Stabilizing System of the Spine, Part I. Function, Dysfunction, Adaptation, and Enhancement, Journal of Spinal Disorders, 1992, vol. 5, No. 4, pp. 383-389.

(22) Filed: **Jul. 26, 2005**

(Continued)

(65) **Prior Publication Data**

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Assistant Examiner—Jan Christopher Merene
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(51) **Int. Cl.**
A61B 17/70 (2006.01)

(57) **ABSTRACT**

(52) **U.S. Cl.** **606/257**; 606/255; 606/263;
606/264

(58) **Field of Classification Search** 606/255,
606/279, 250–254, 246, 256–278, 914–916;
403/229

See application file for complete search history.

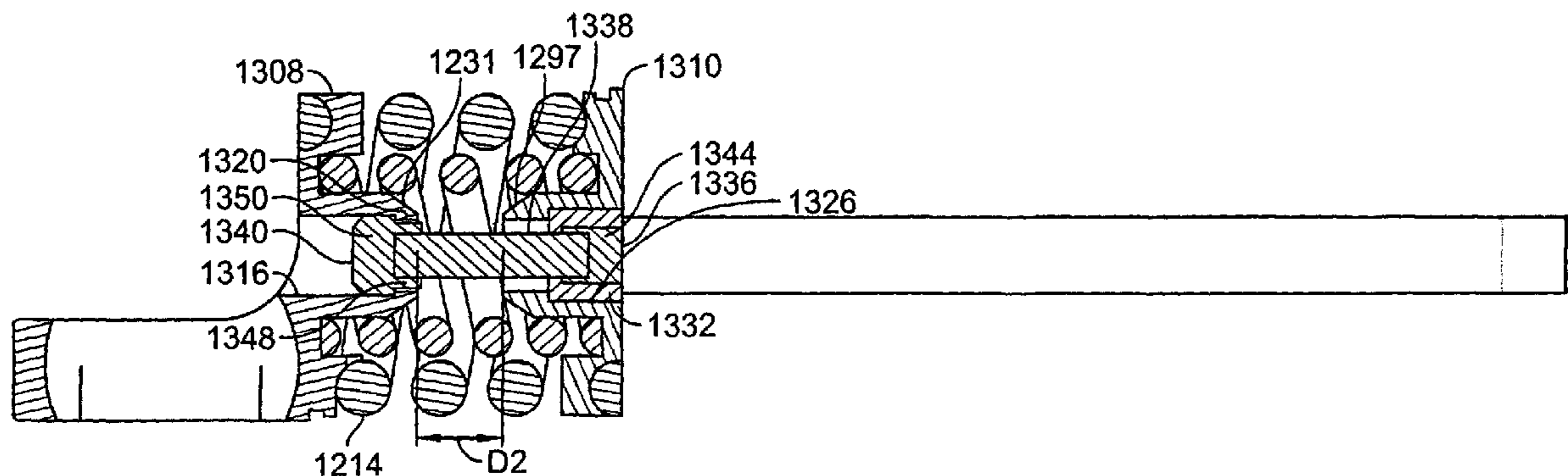
Spinal stabilization devices, systems and methods are provided that include a stabilization member including a first structural member that mounts to a pedicle screw, a second structural member adjacent the first structural member and that can move away therefrom, a resilient element mounted between the structural members and that elongates to accommodate relative movement therebetween, and a travel-limiting structure mounted between the structural members and that defines and imposes upon the stabilization member a maximum distance by which the first and second structural members may be separated. The travel-limiting structure can include an axially inextensible, laterally flexible elongate element, e.g., wire-rope cable, disposed between the structural members. The resilient element extends between respective first ends of the structural members, while the travel-limiting structure can include terminations at opposite ends of the elongate element and mounted to respective second ends of the structural members opposite the first ends thereof.

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21 Claims, 30 Drawing Sheets



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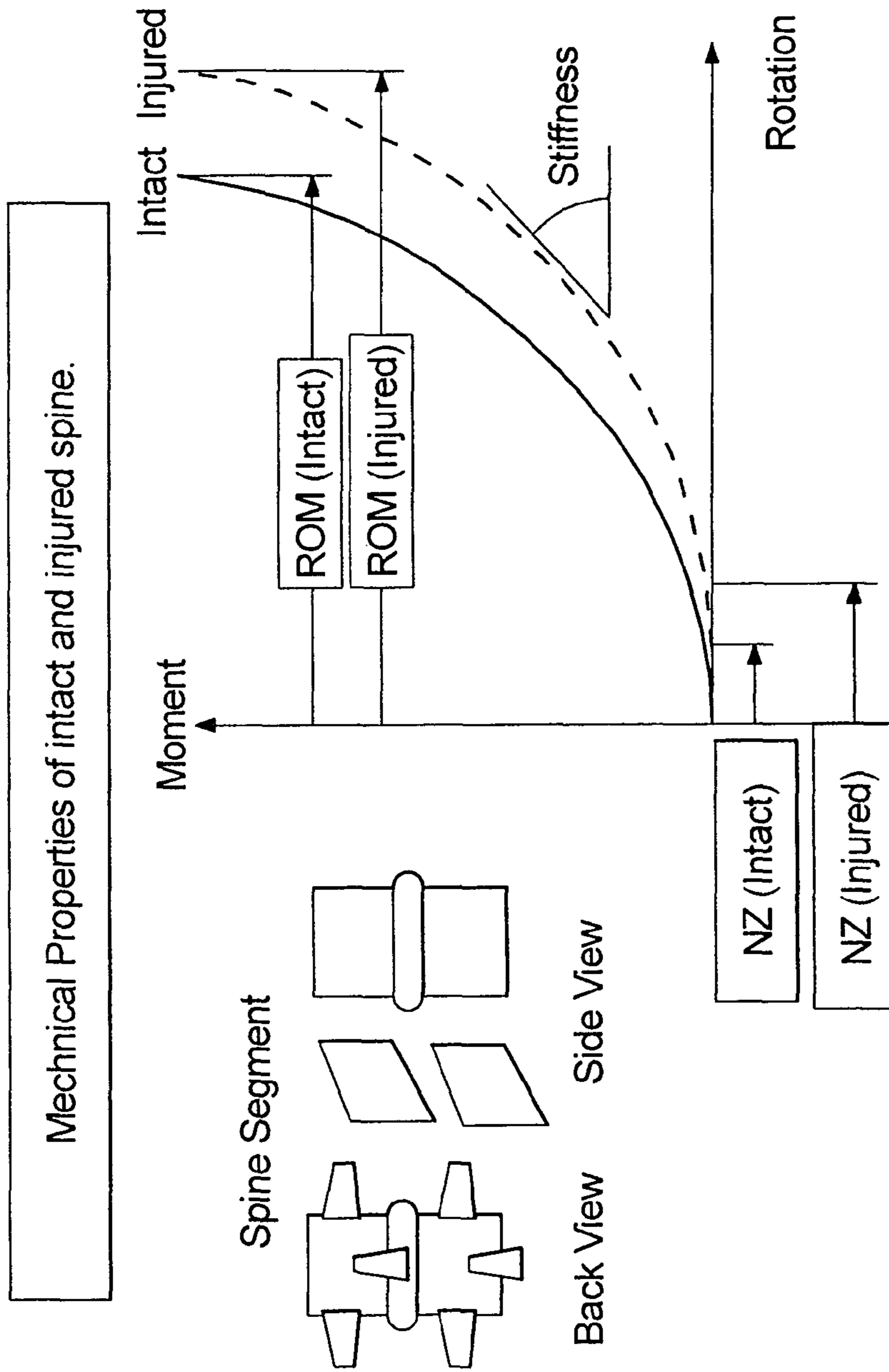


FIG. 1

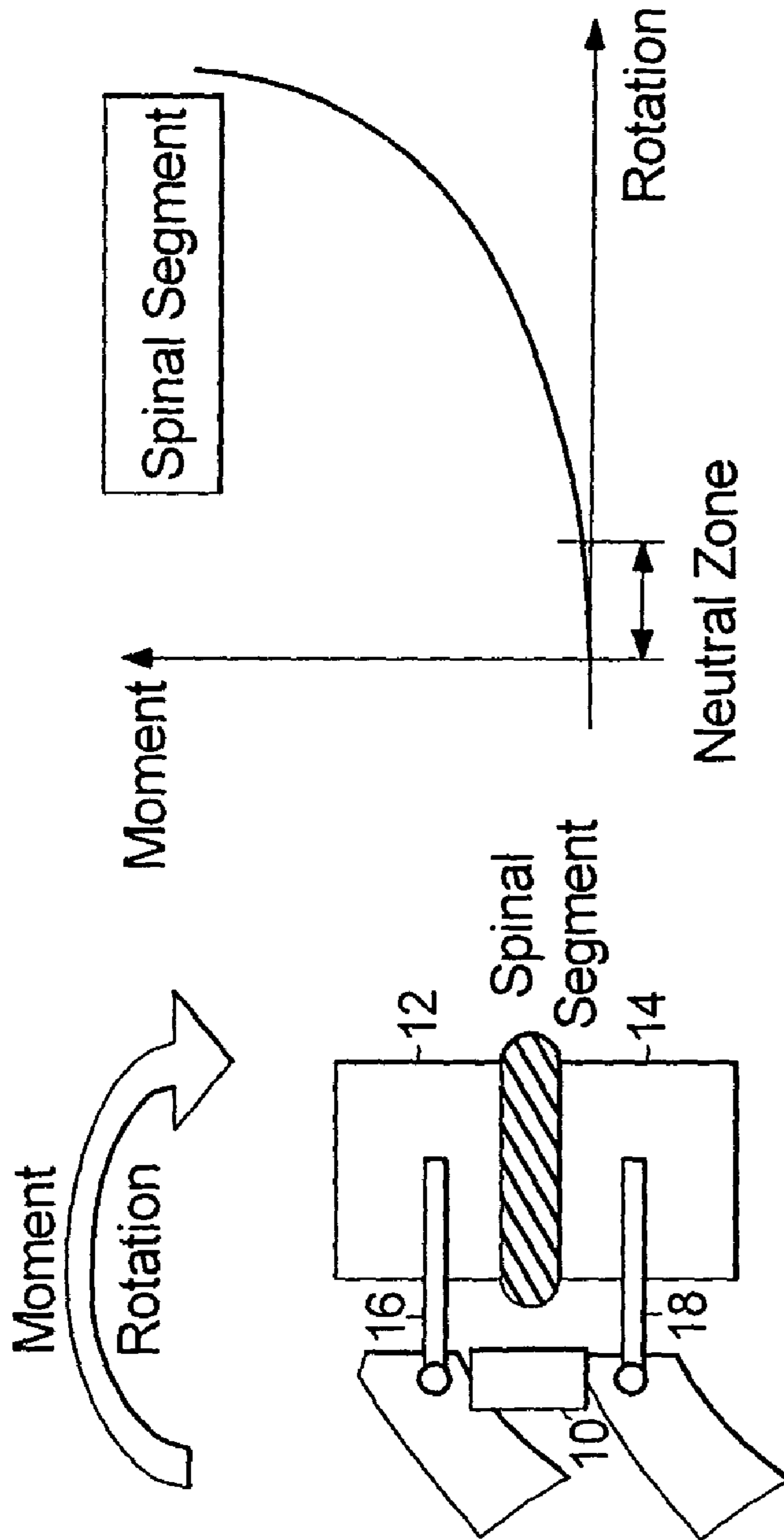


FIG. 2

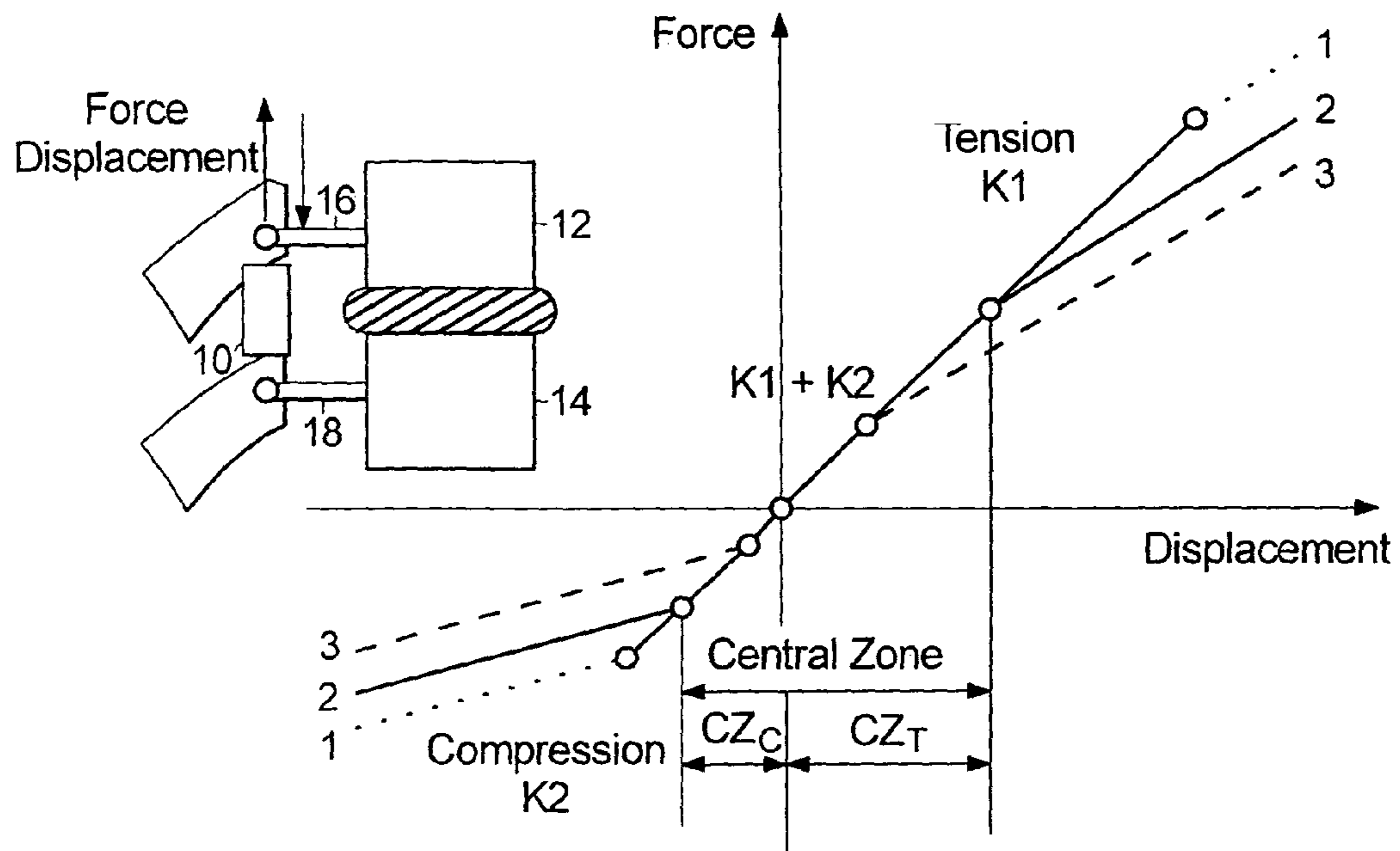


FIG. 3a

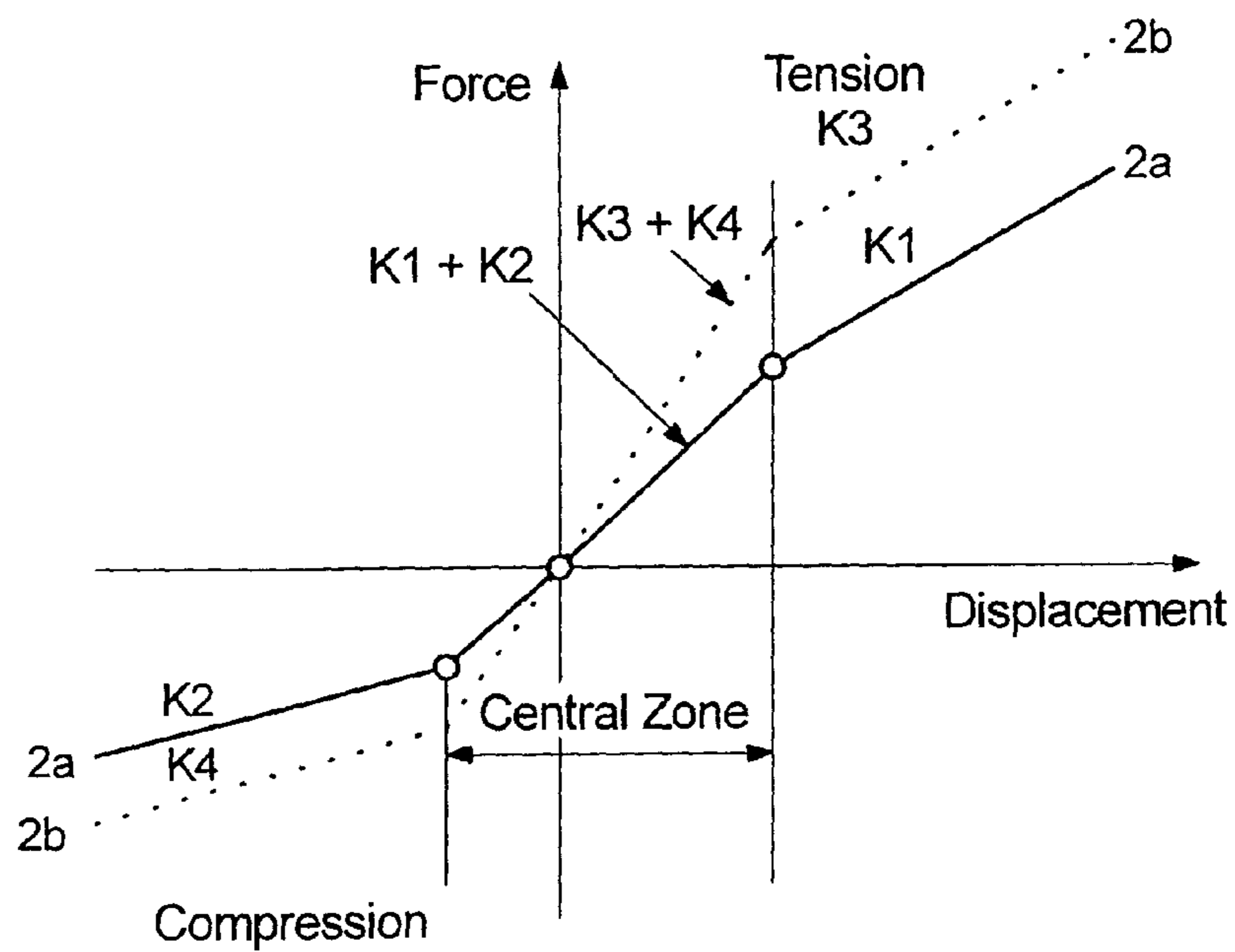


FIG. 3b

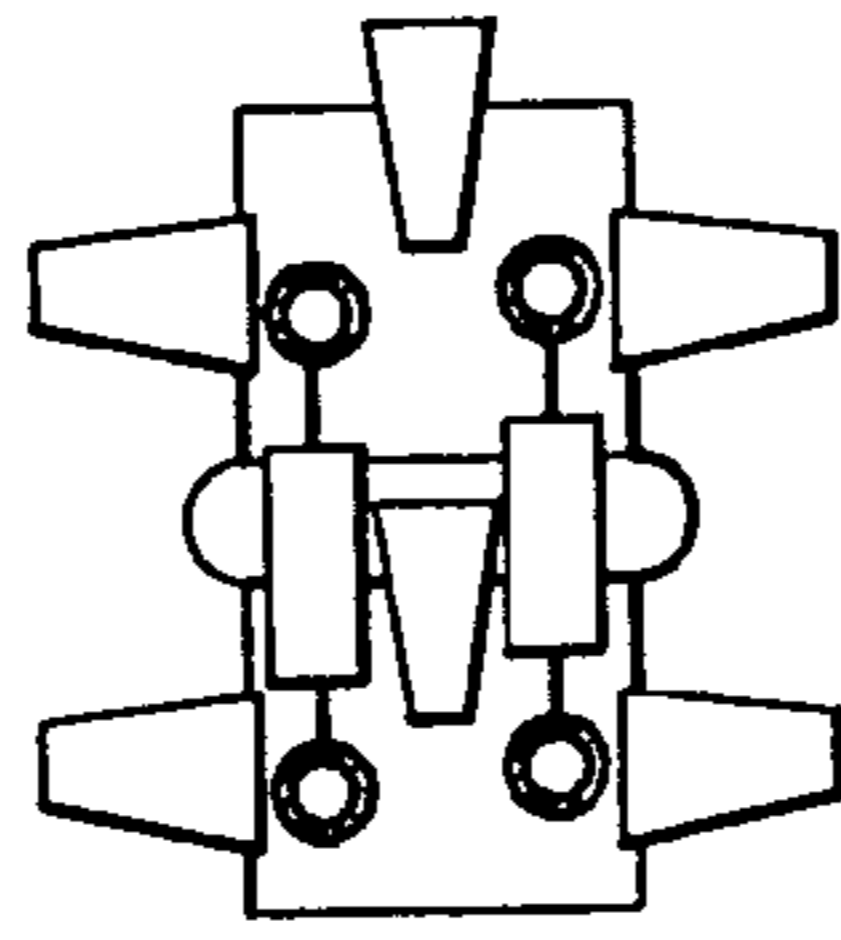


FIG. 3c

DSS in Tension

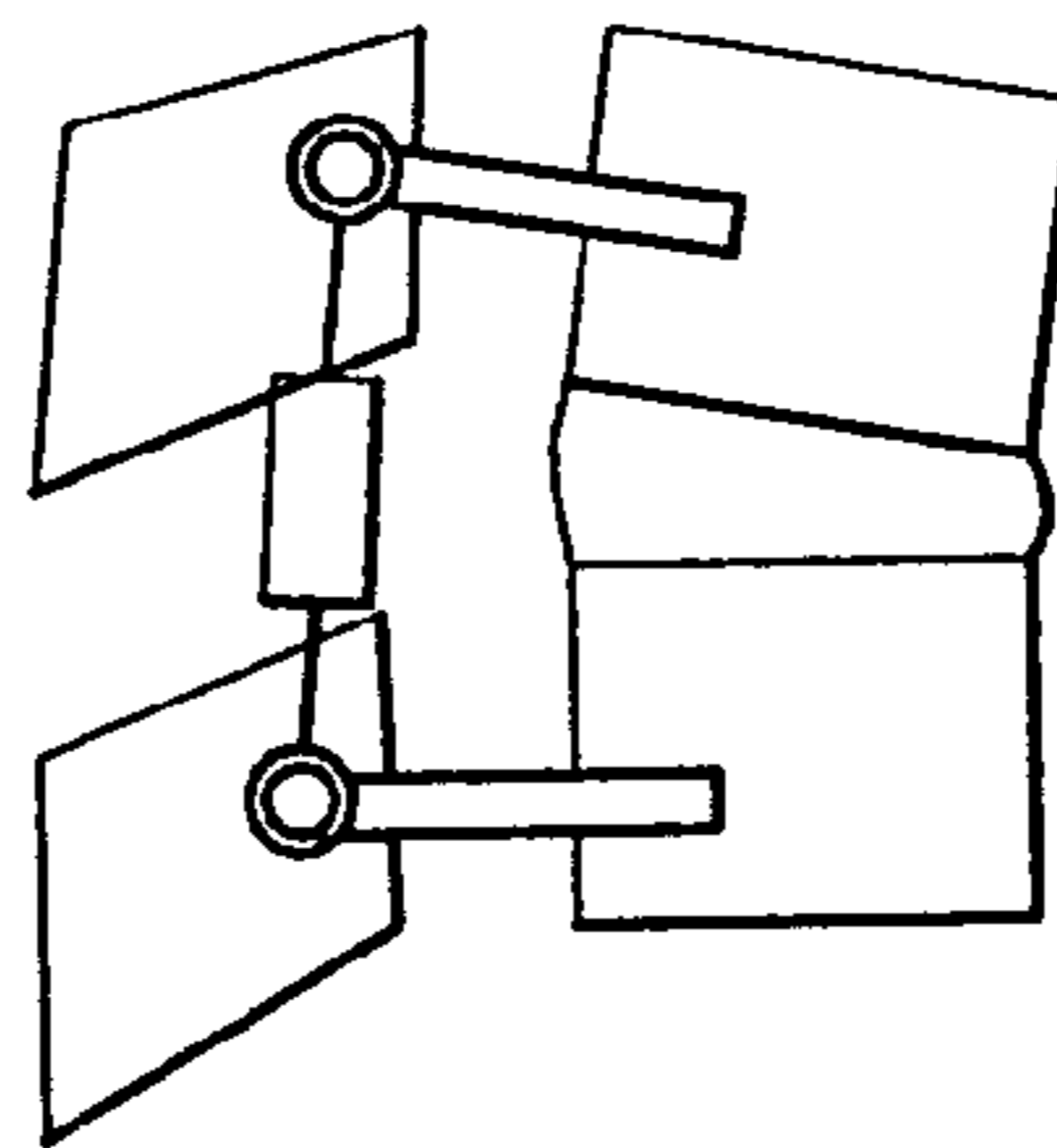


FIG. 3d

DSS in Tension

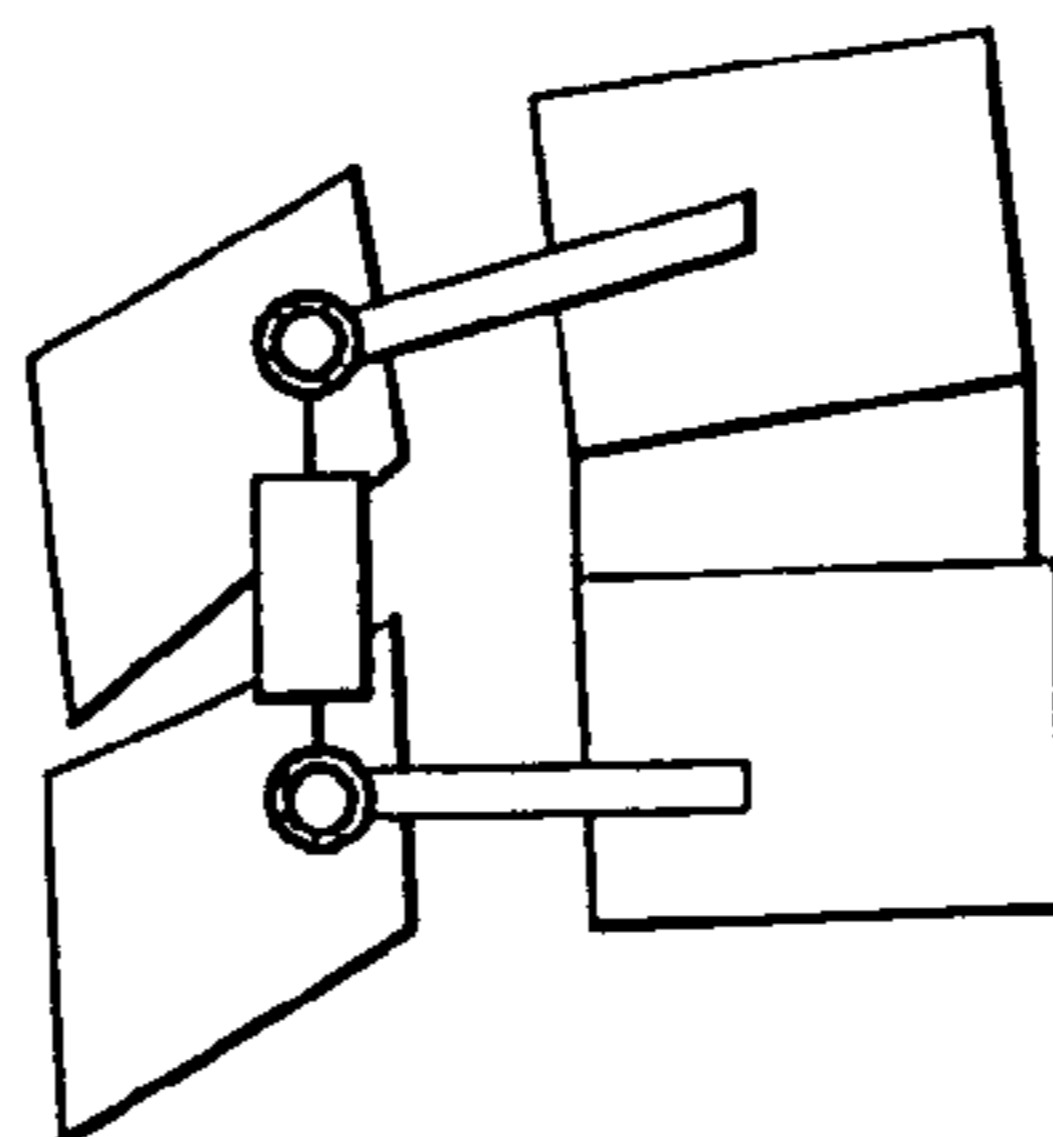


FIG. 3e

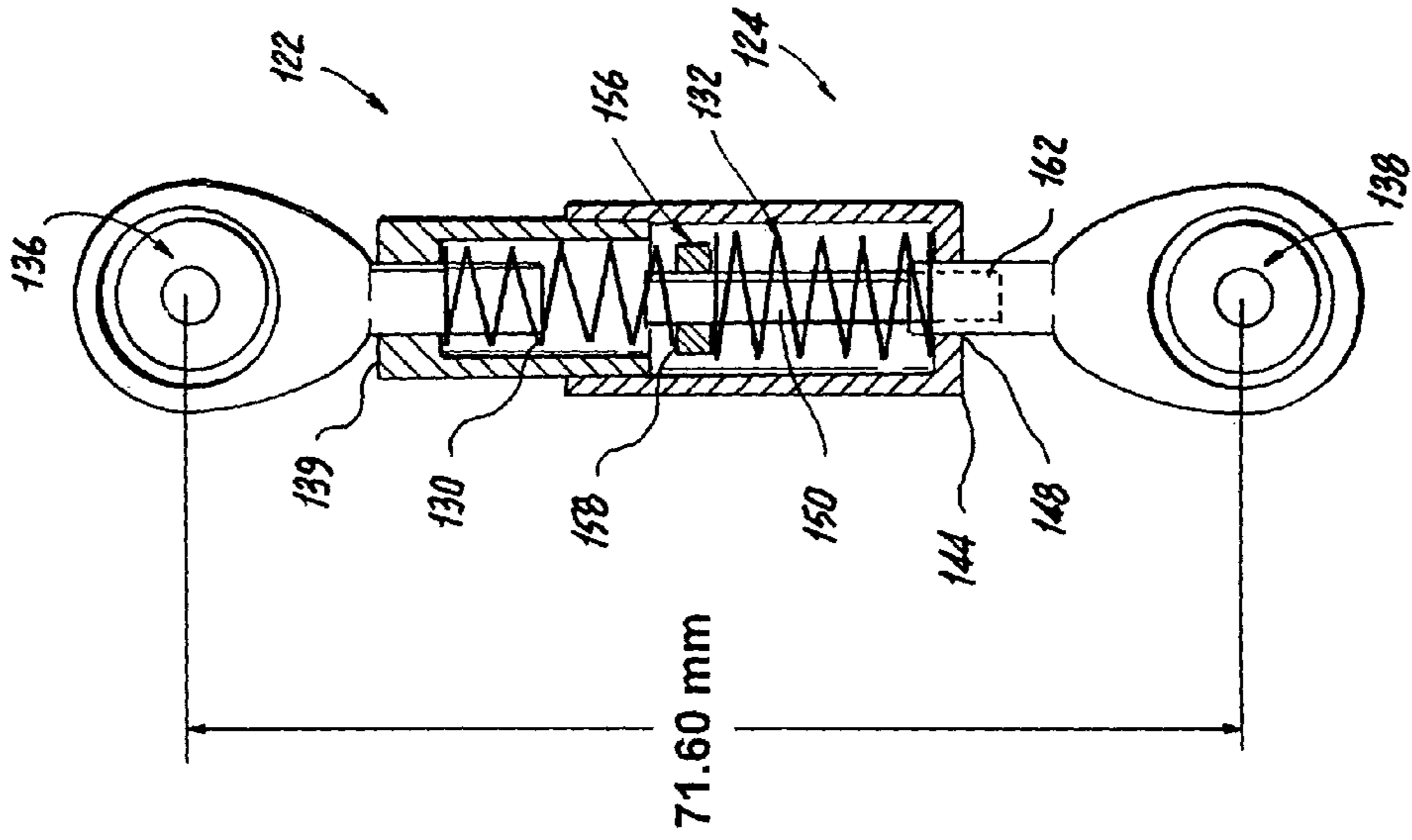


FIG. 5

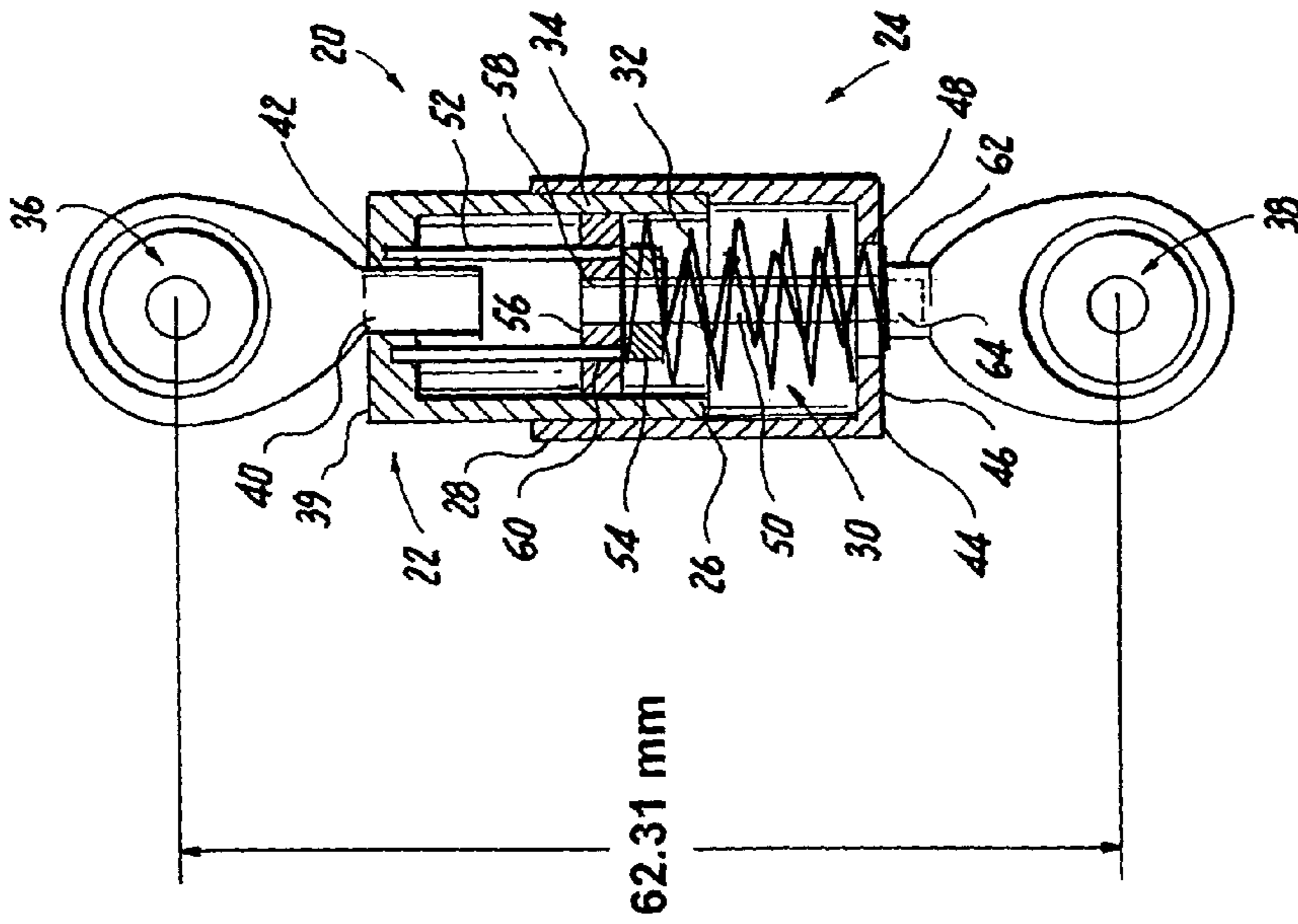


FIG. 4

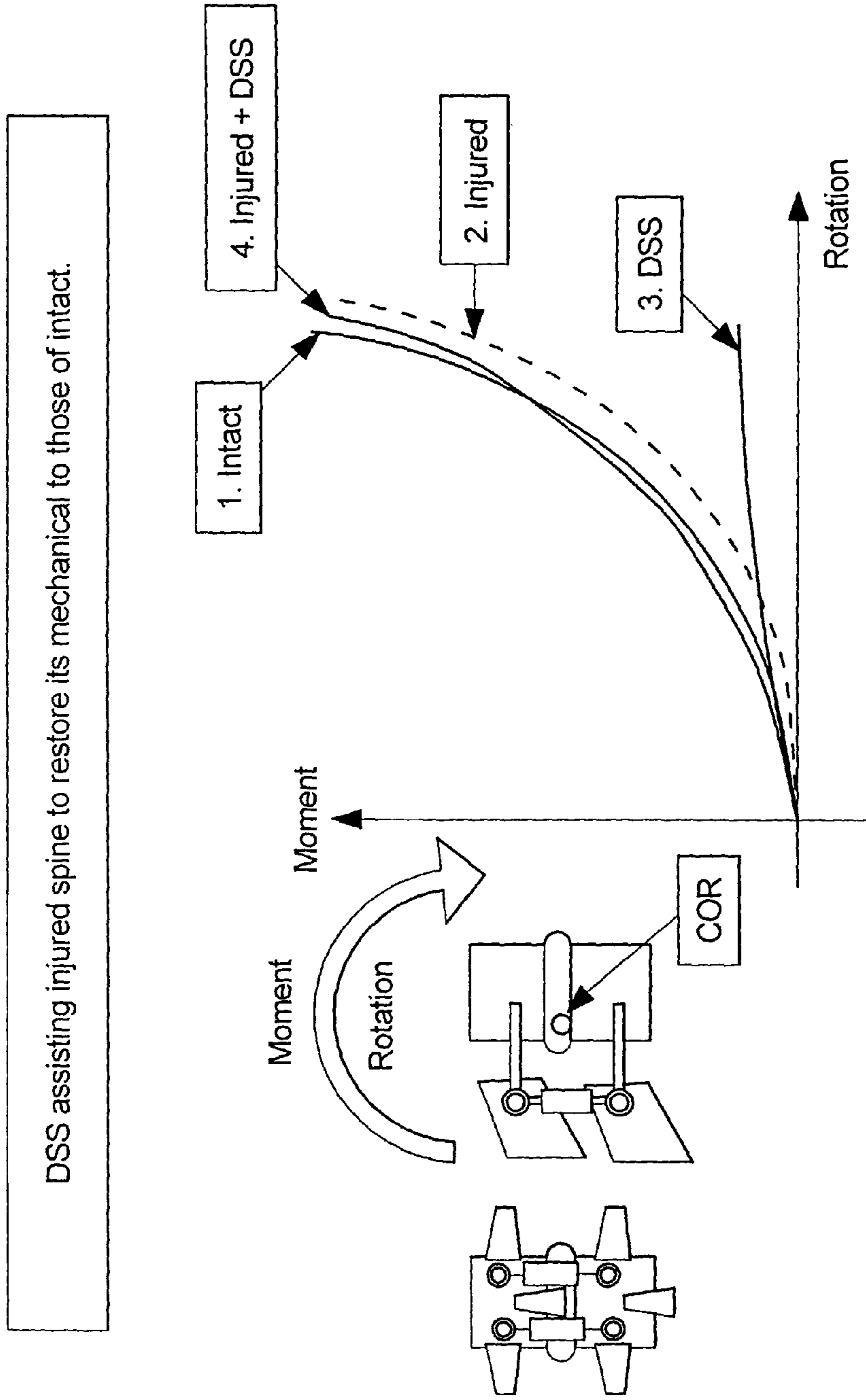
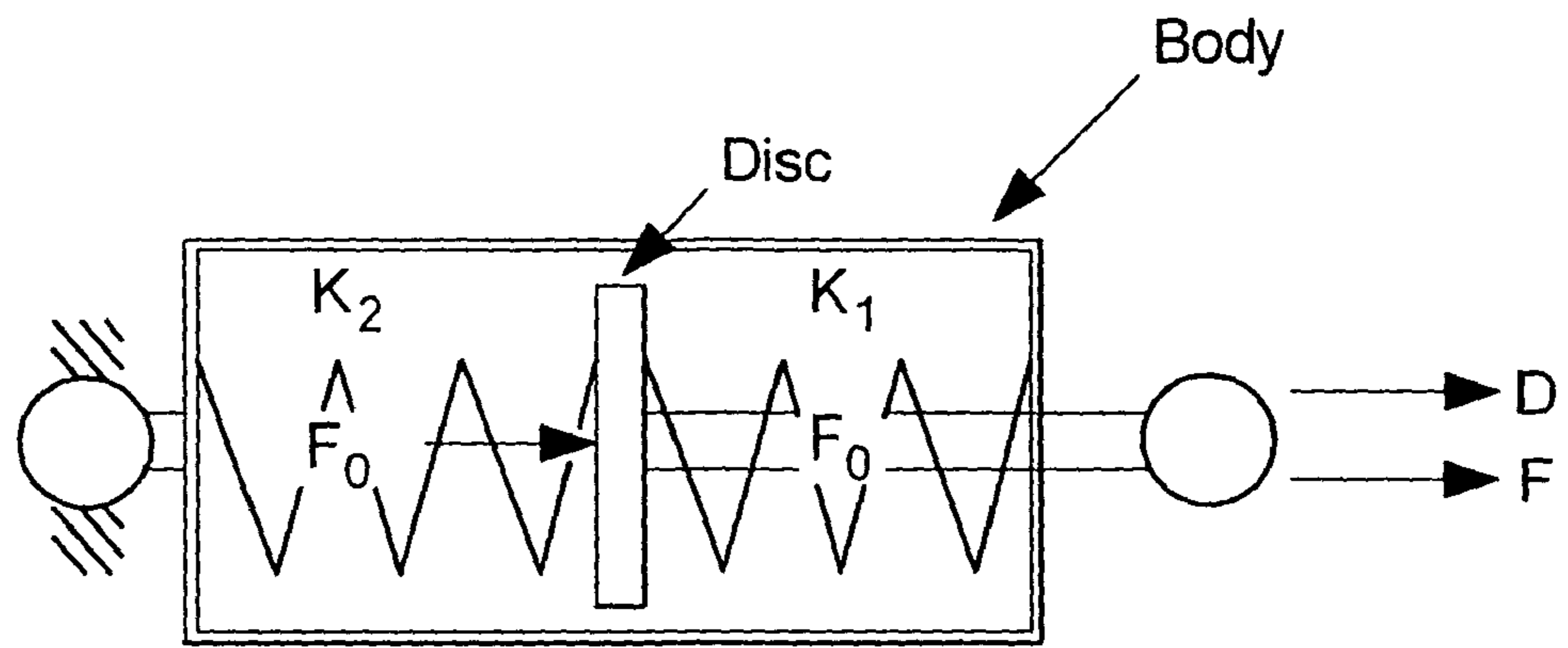


FIG. 6



Free-body diagram

FIG. 7a

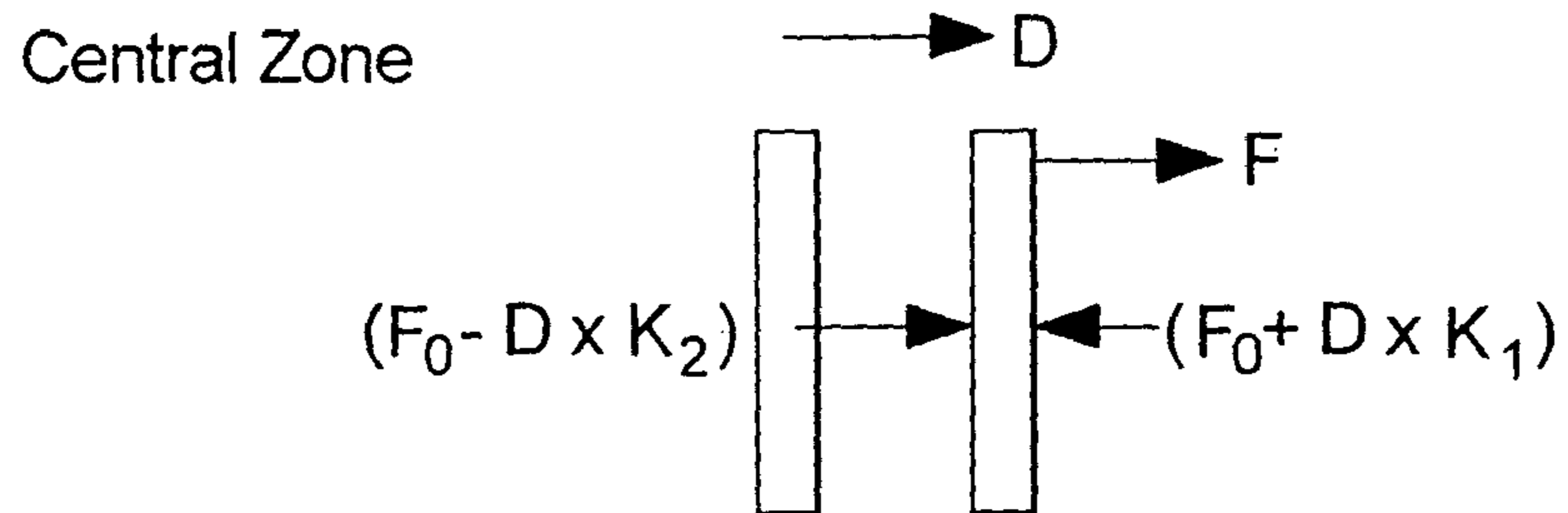


FIG. 7b

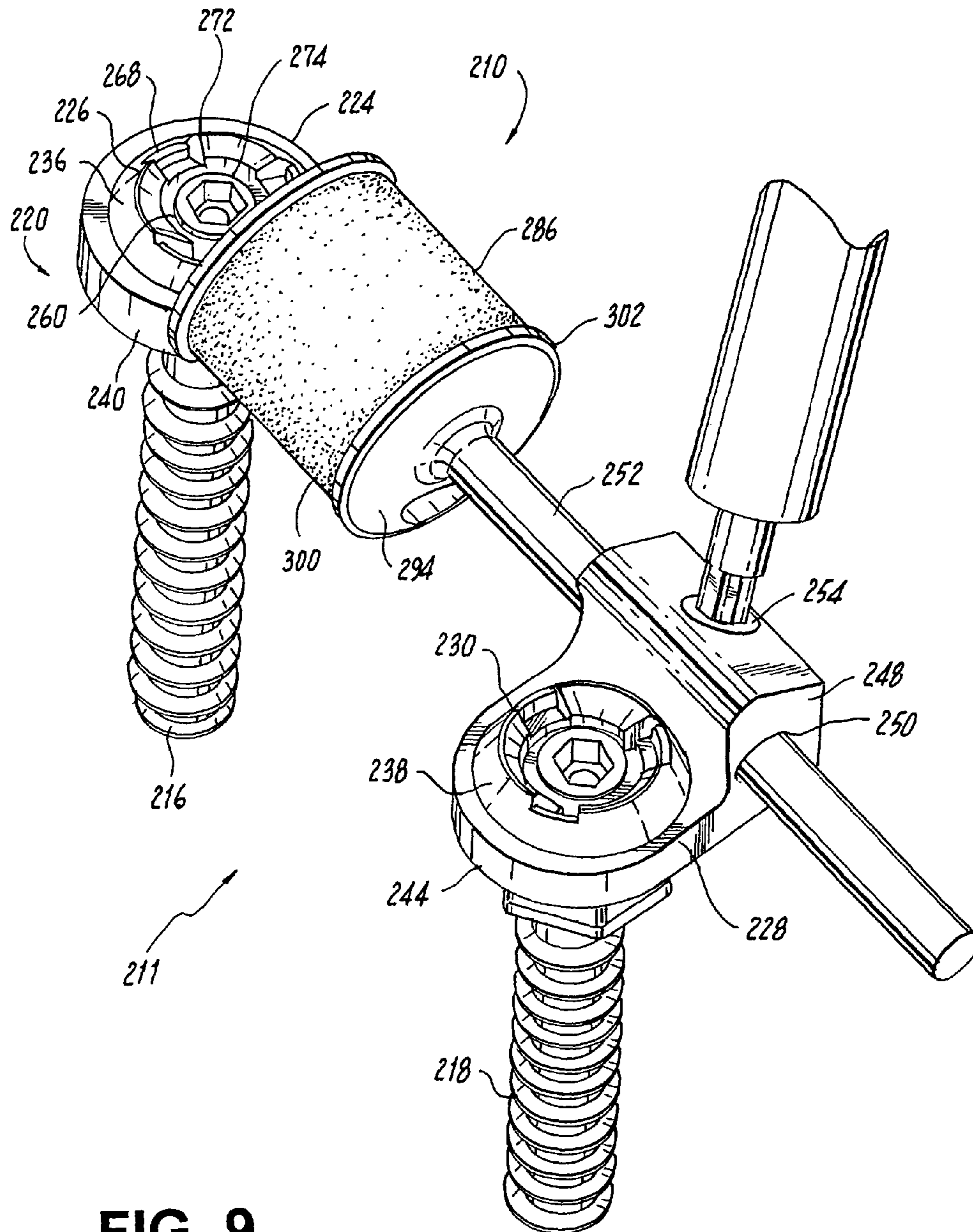


FIG. 9

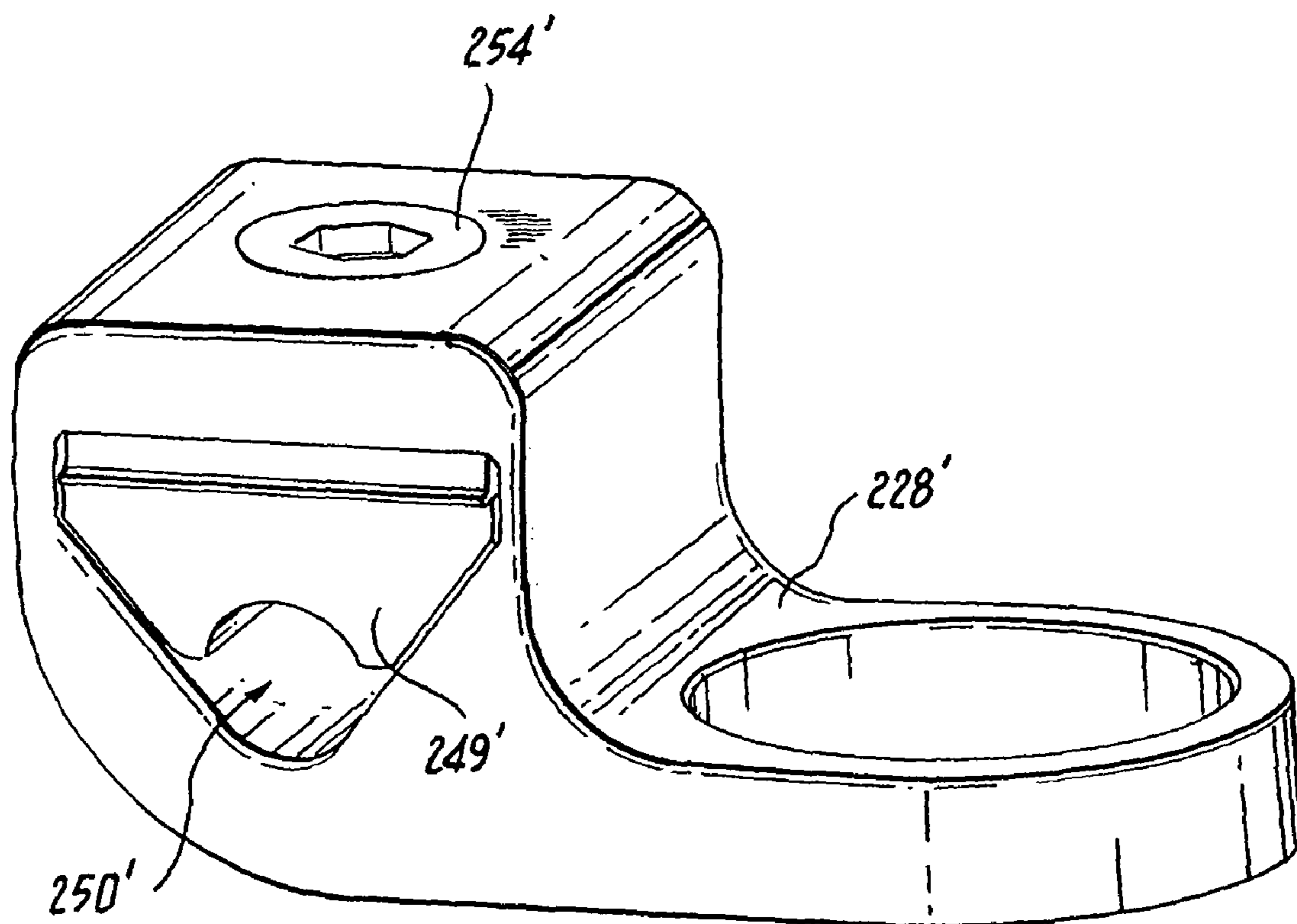


FIG. 10

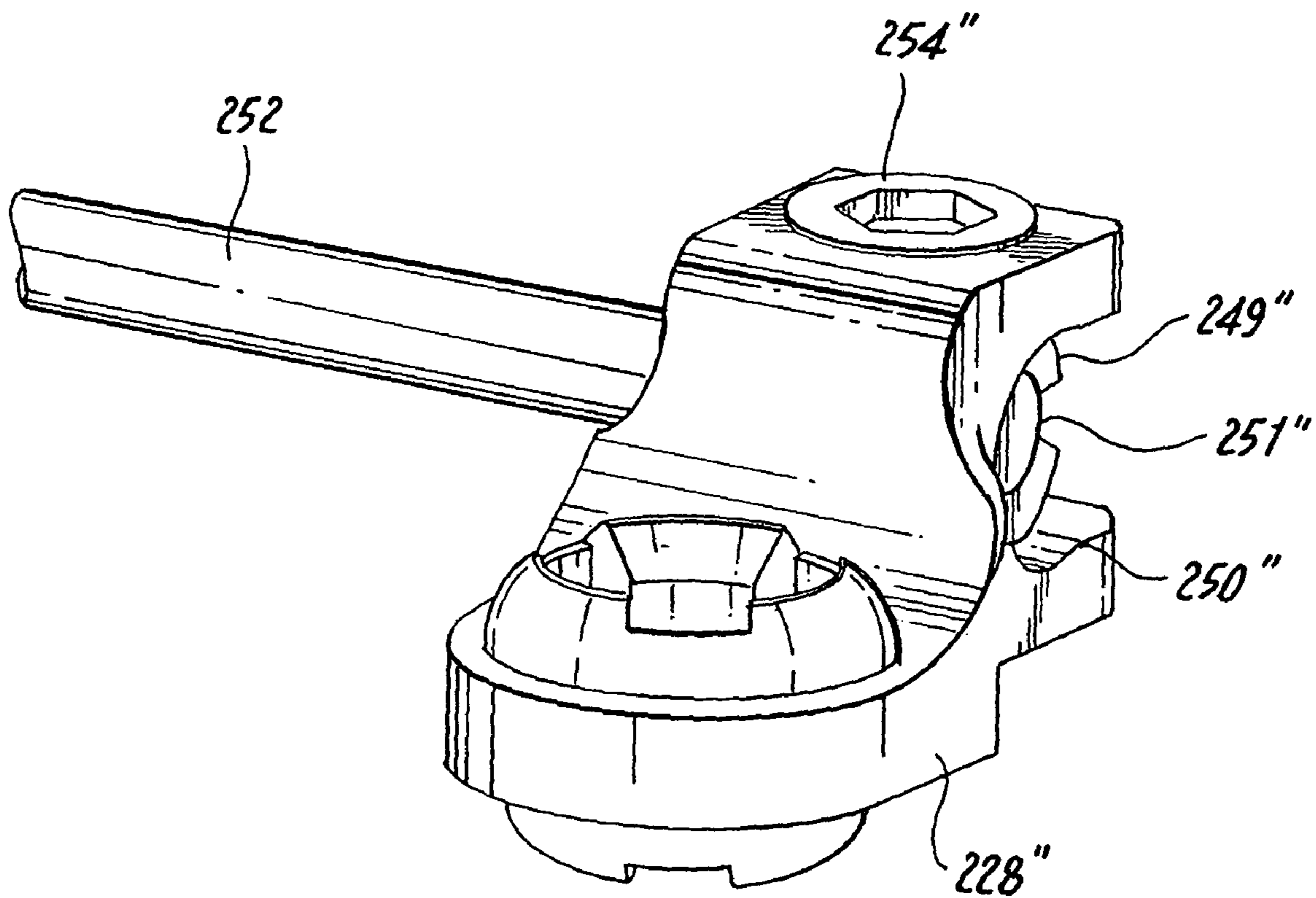


FIG. 11

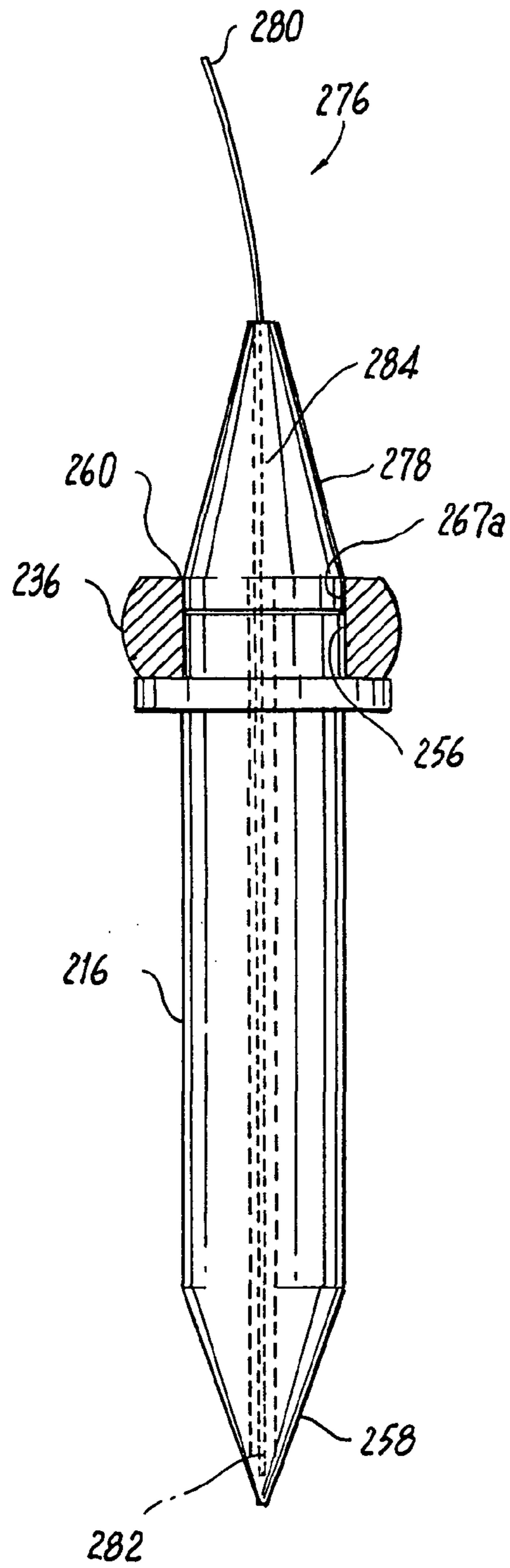


FIG. 12

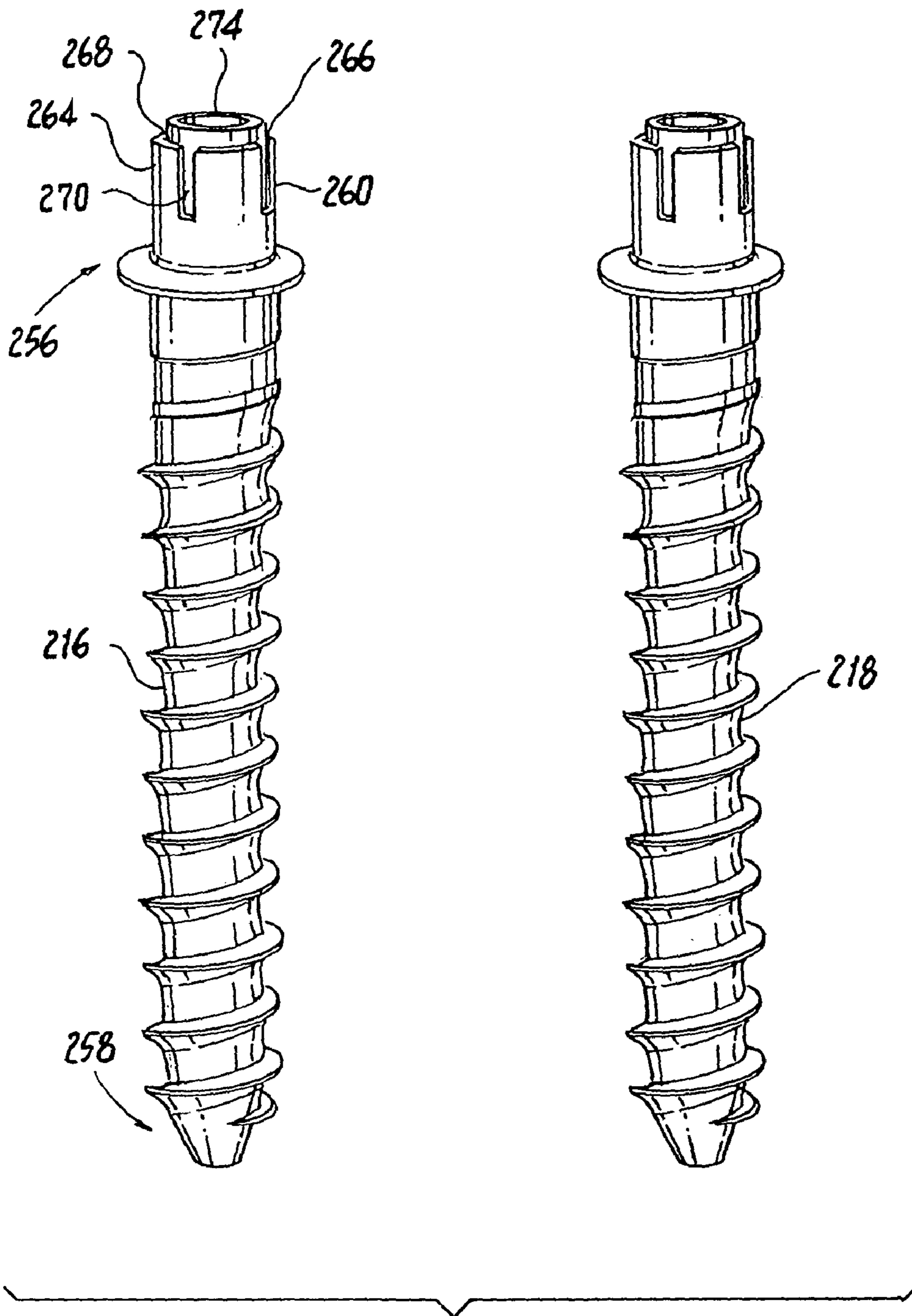


FIG. 13

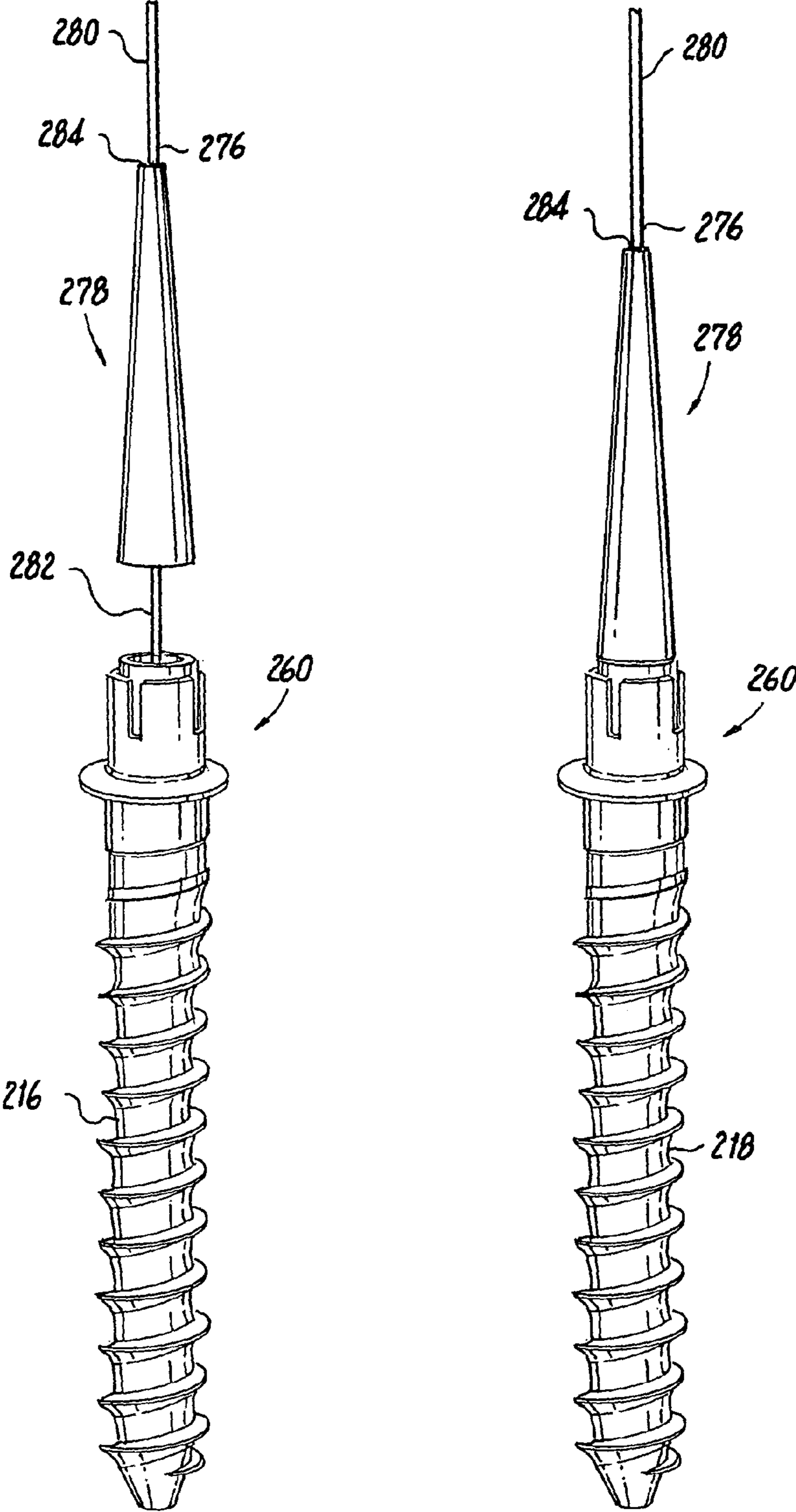


FIG. 14

FIG. 15a

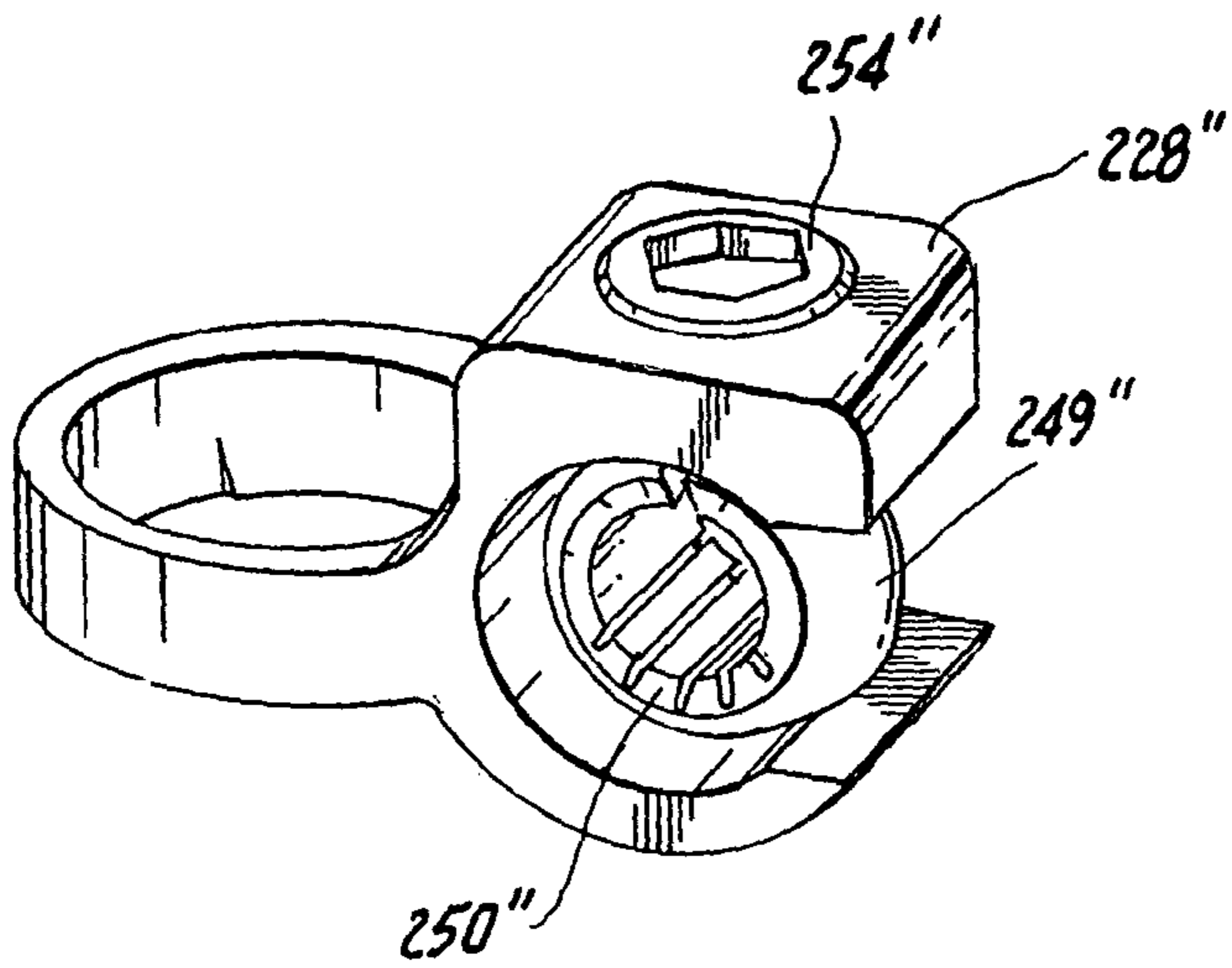
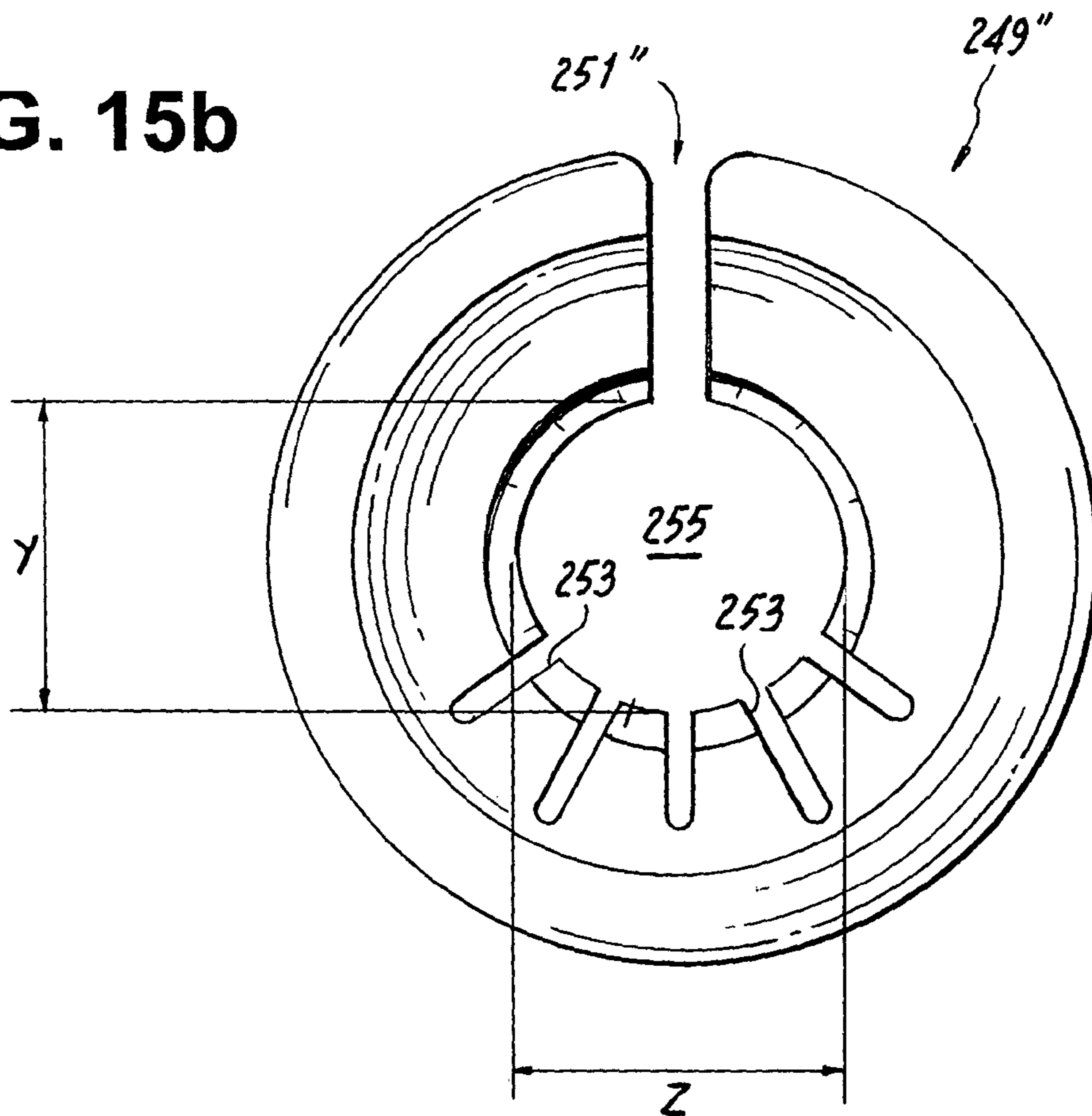


FIG. 15b



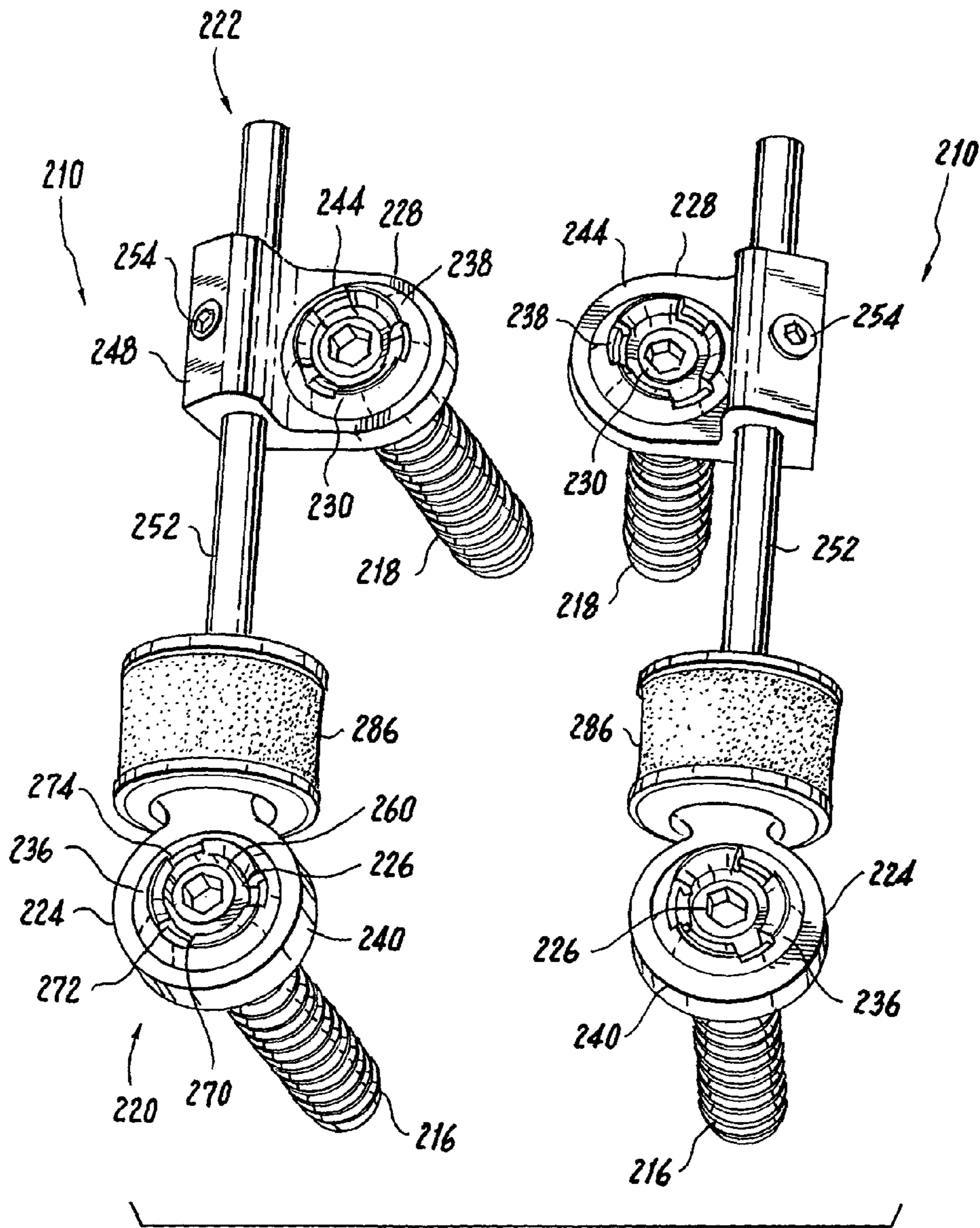


FIG. 16

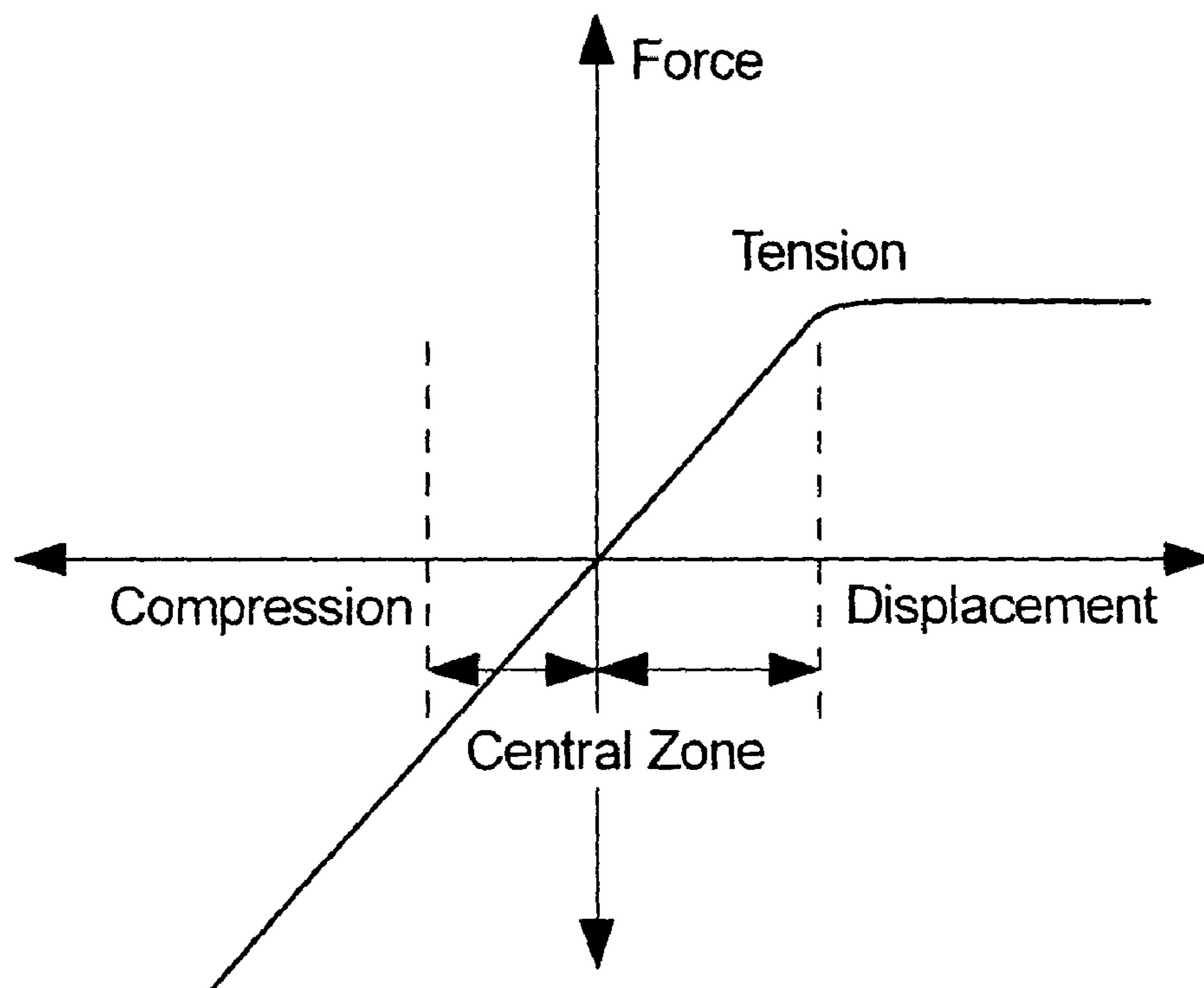


FIG. 17

FIG. 18

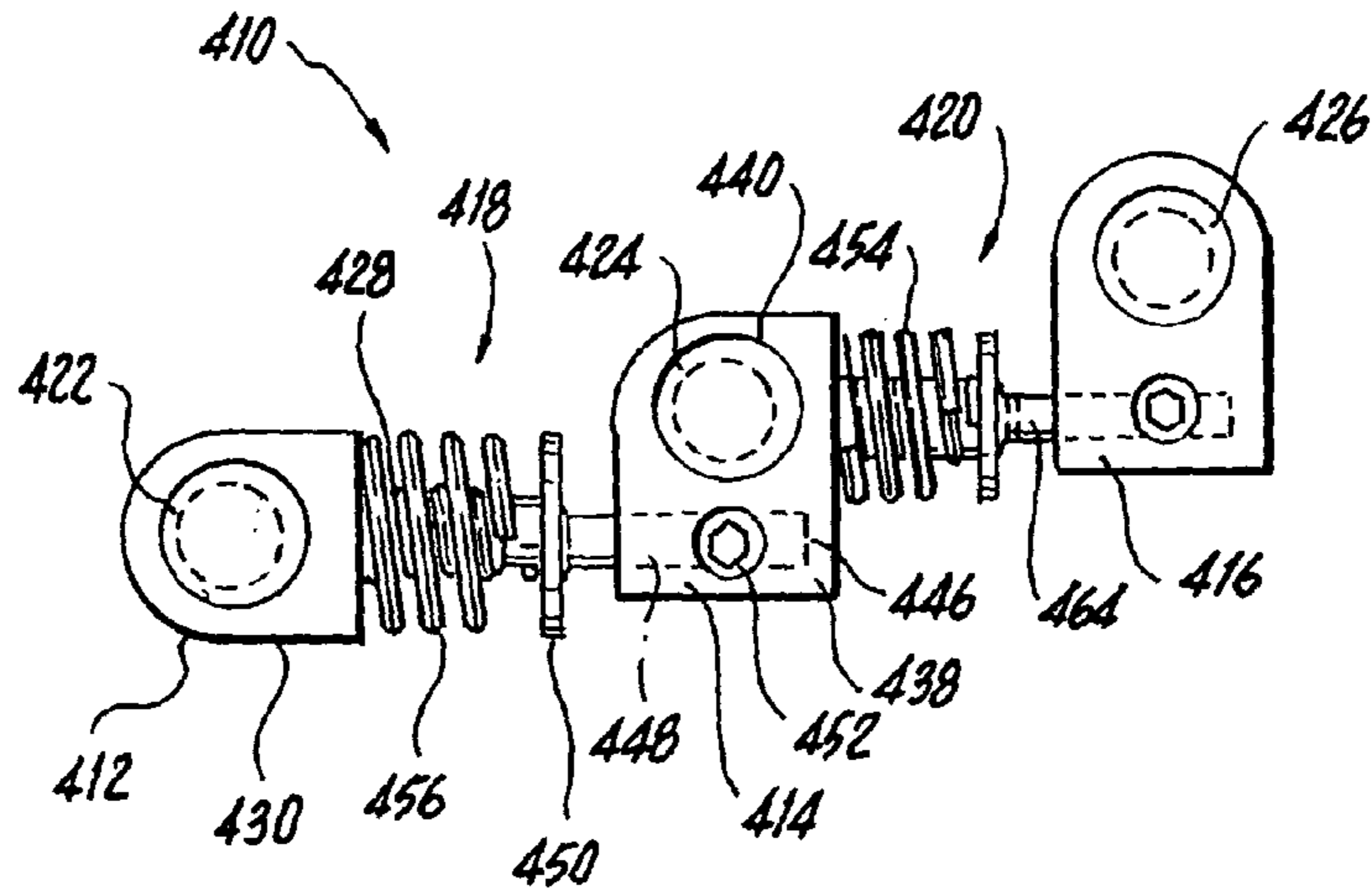


FIG. 19

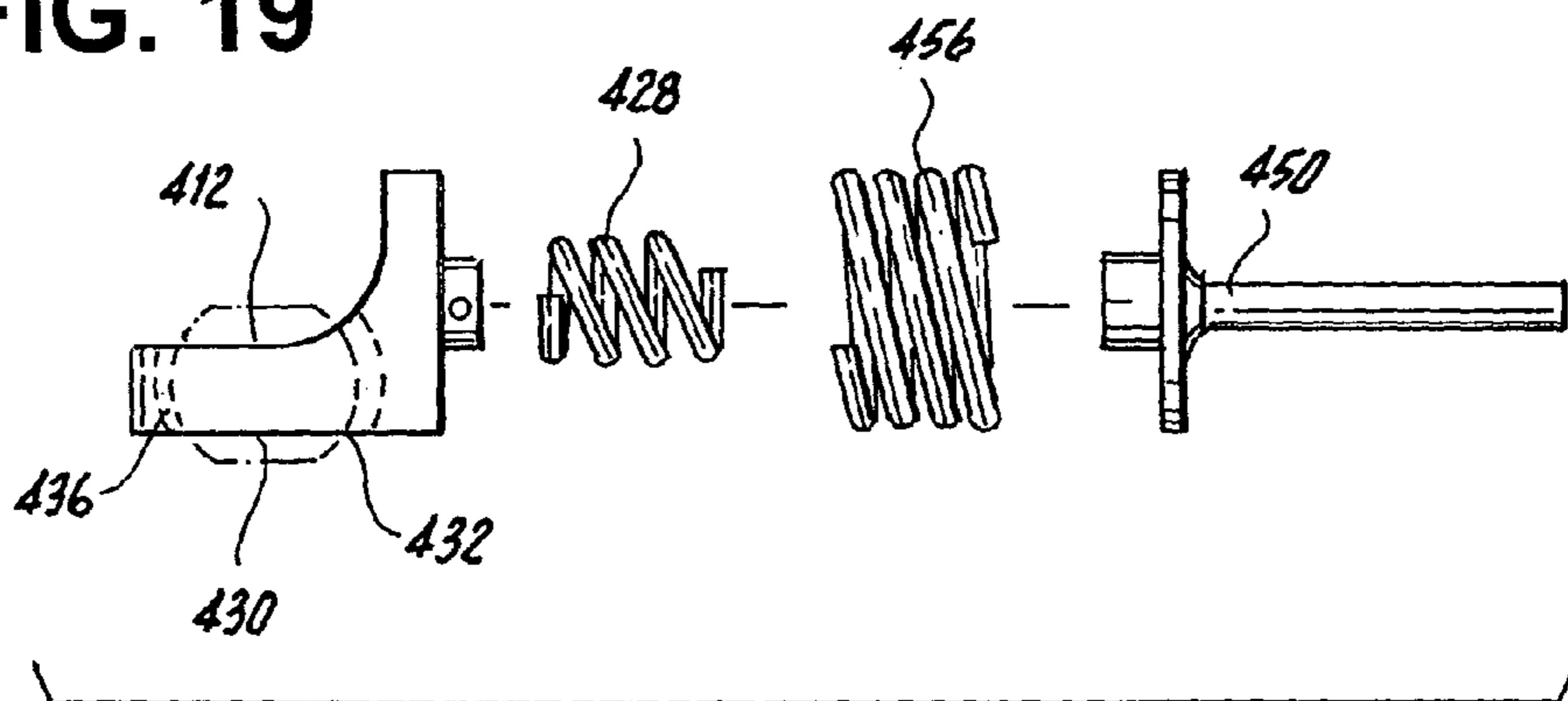
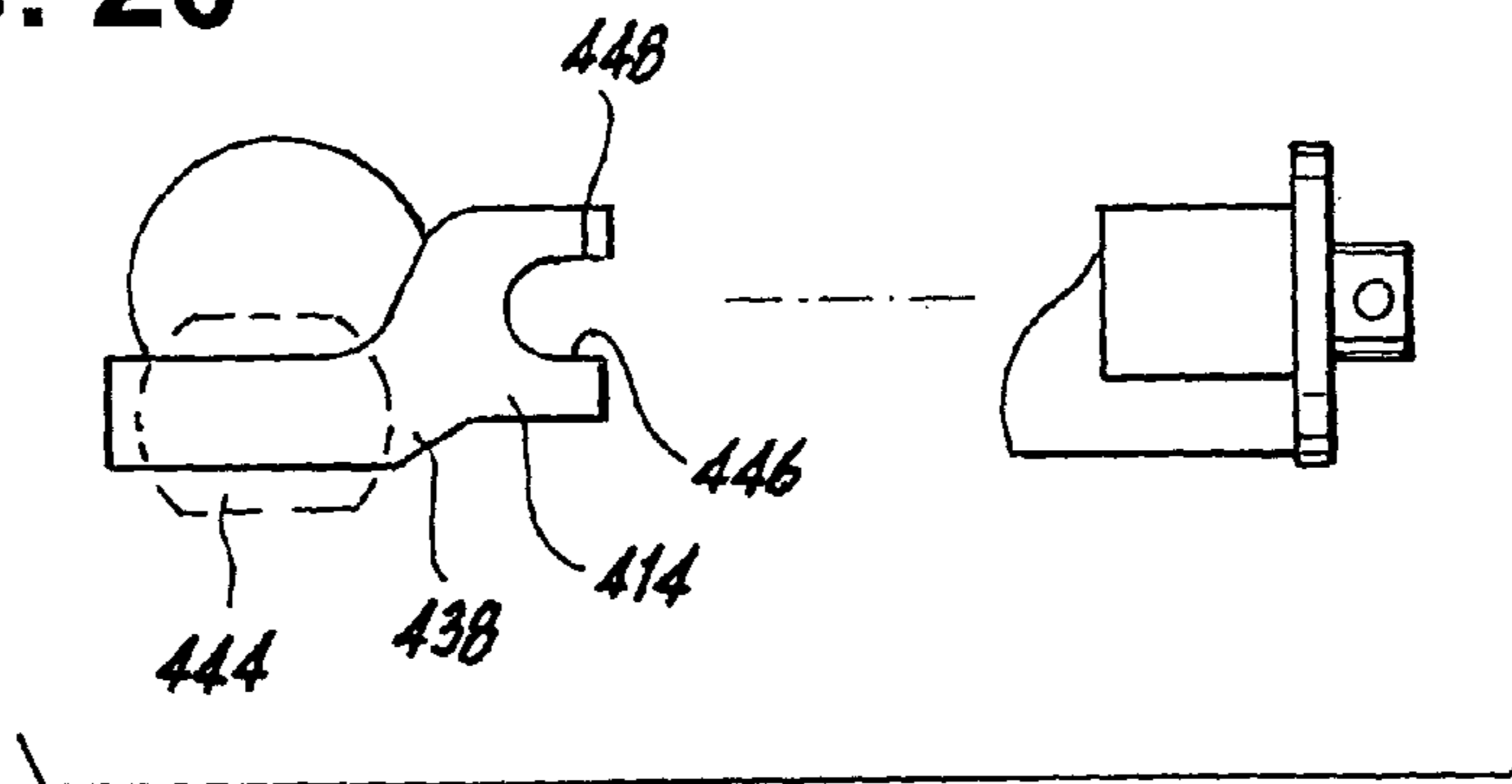


FIG. 20



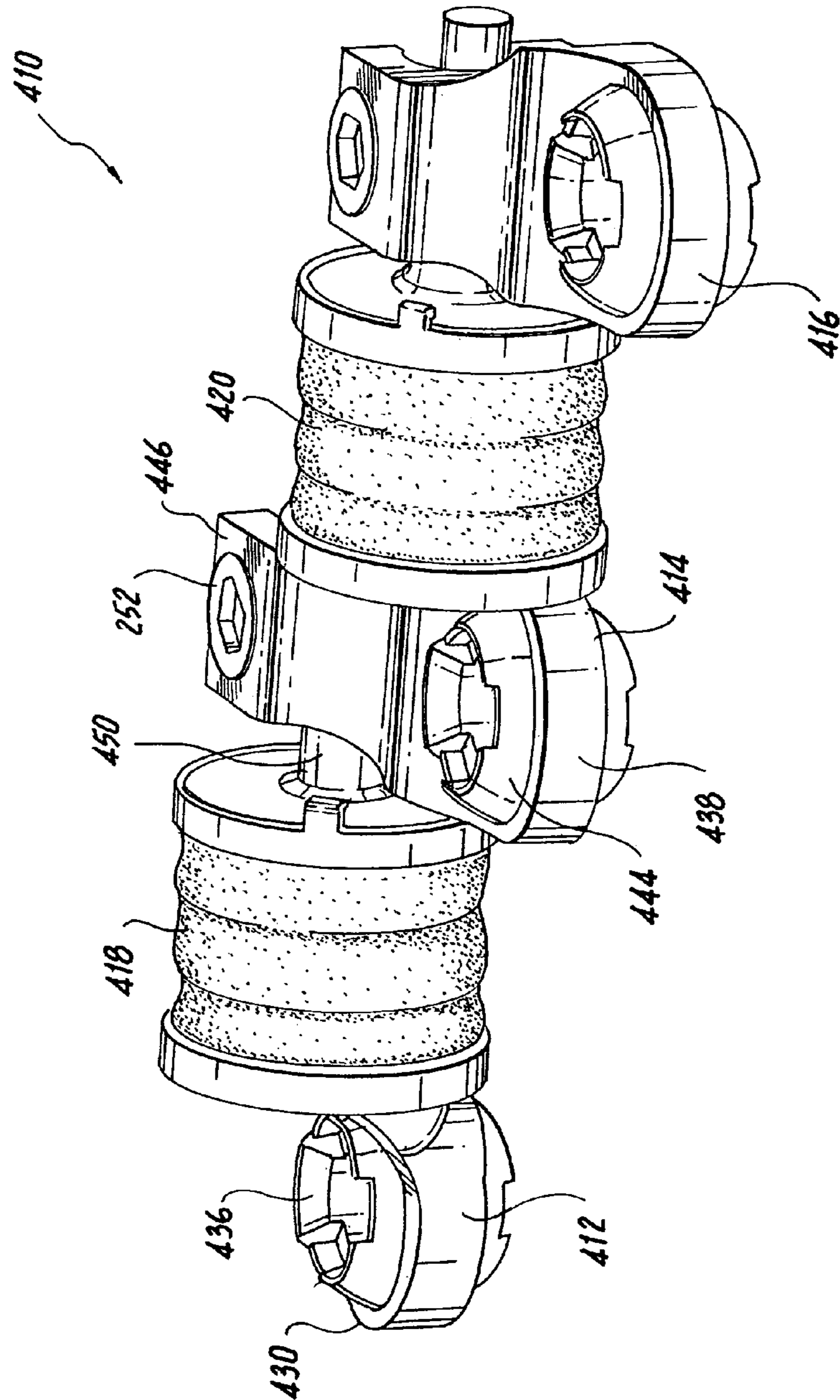


FIG. 21

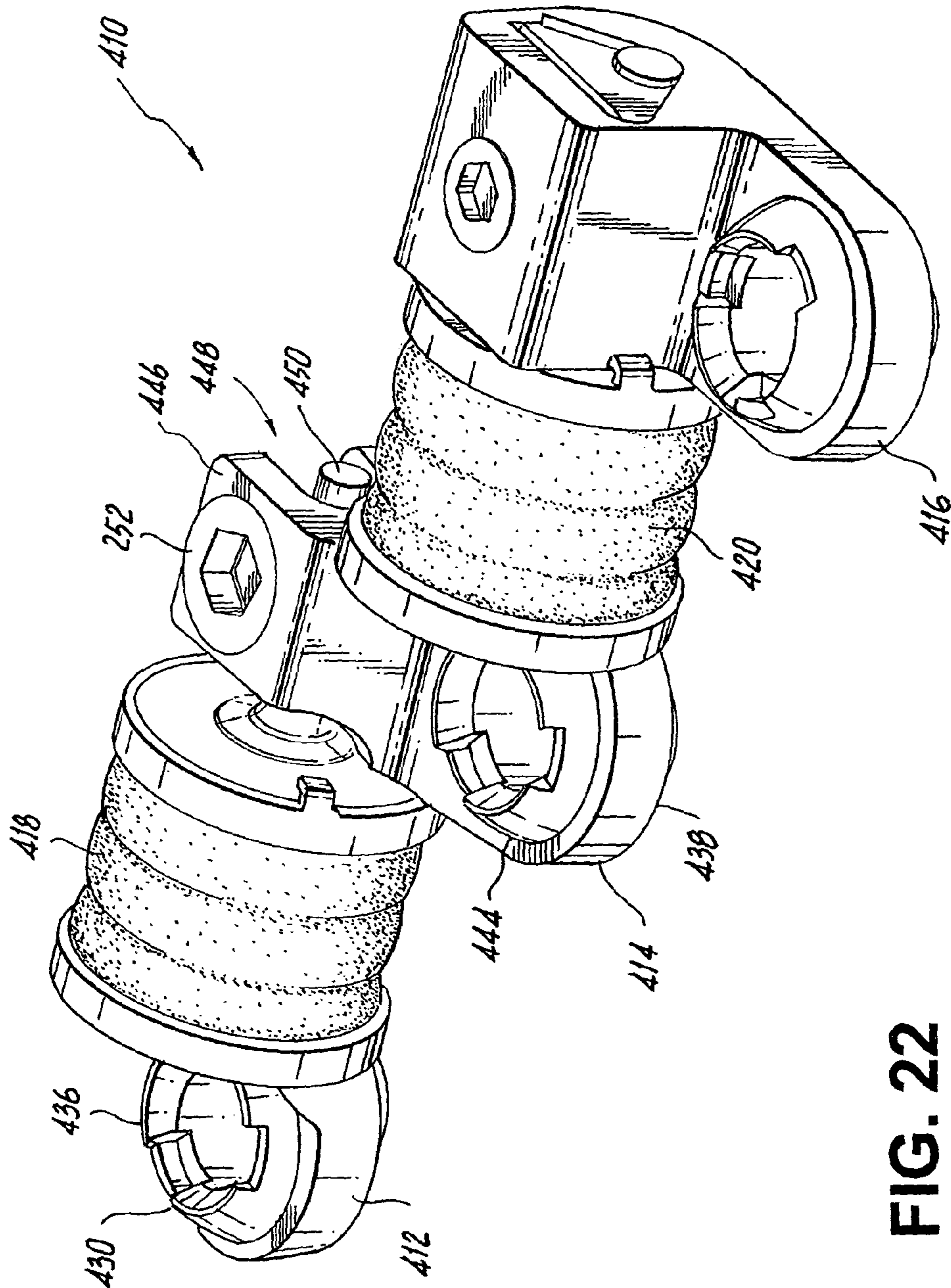


FIG. 22

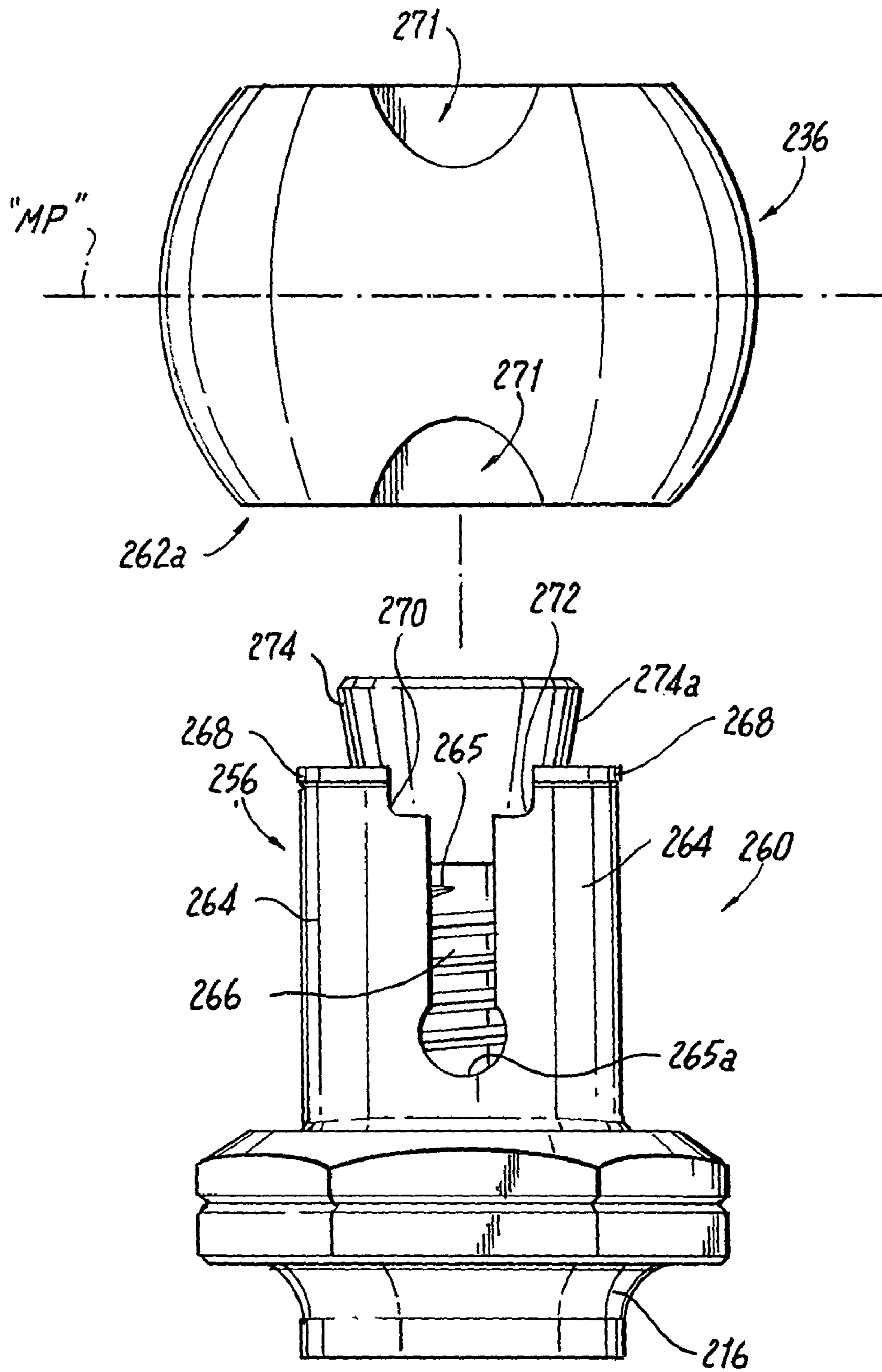


FIG. 23

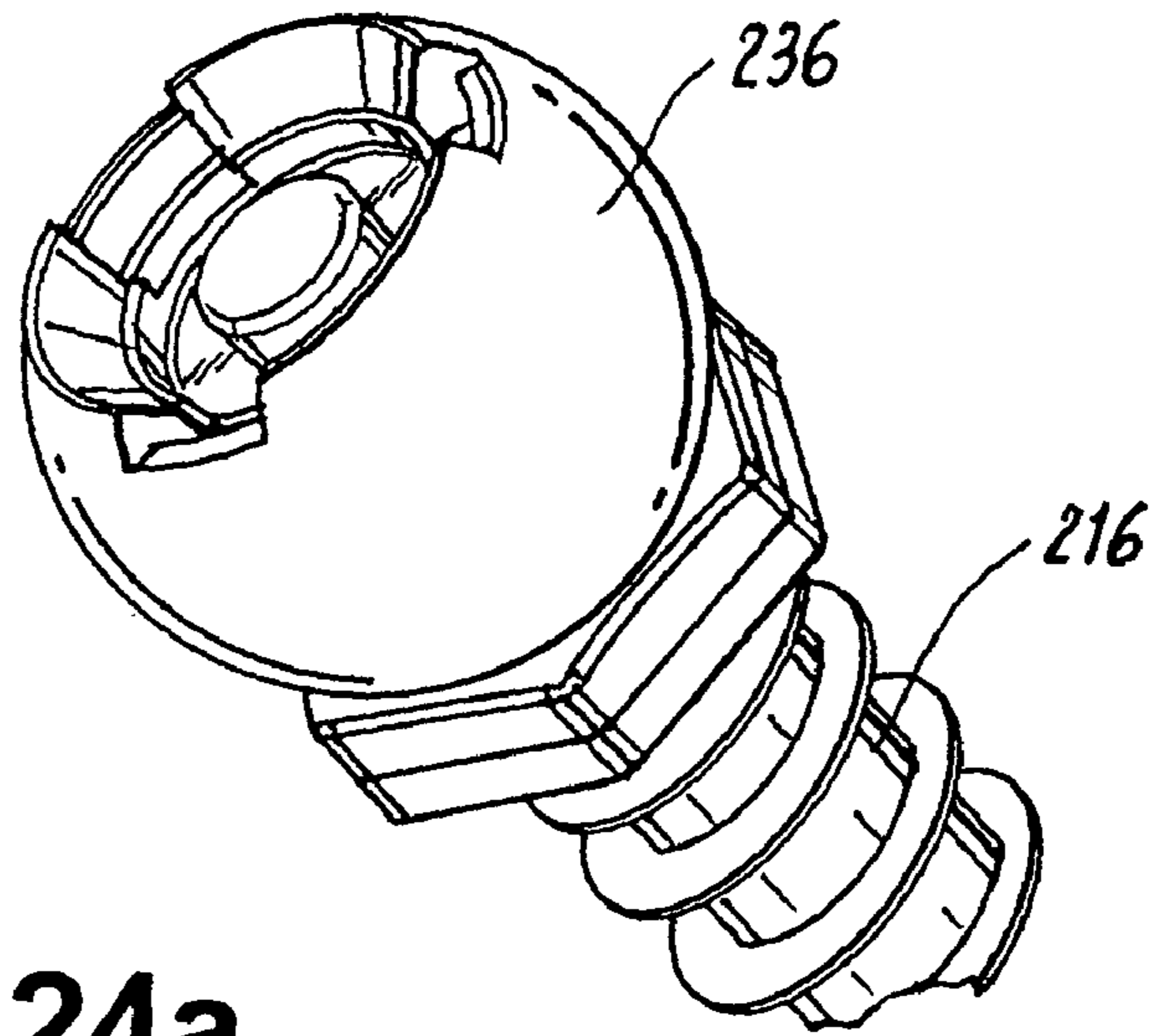


FIG. 24a

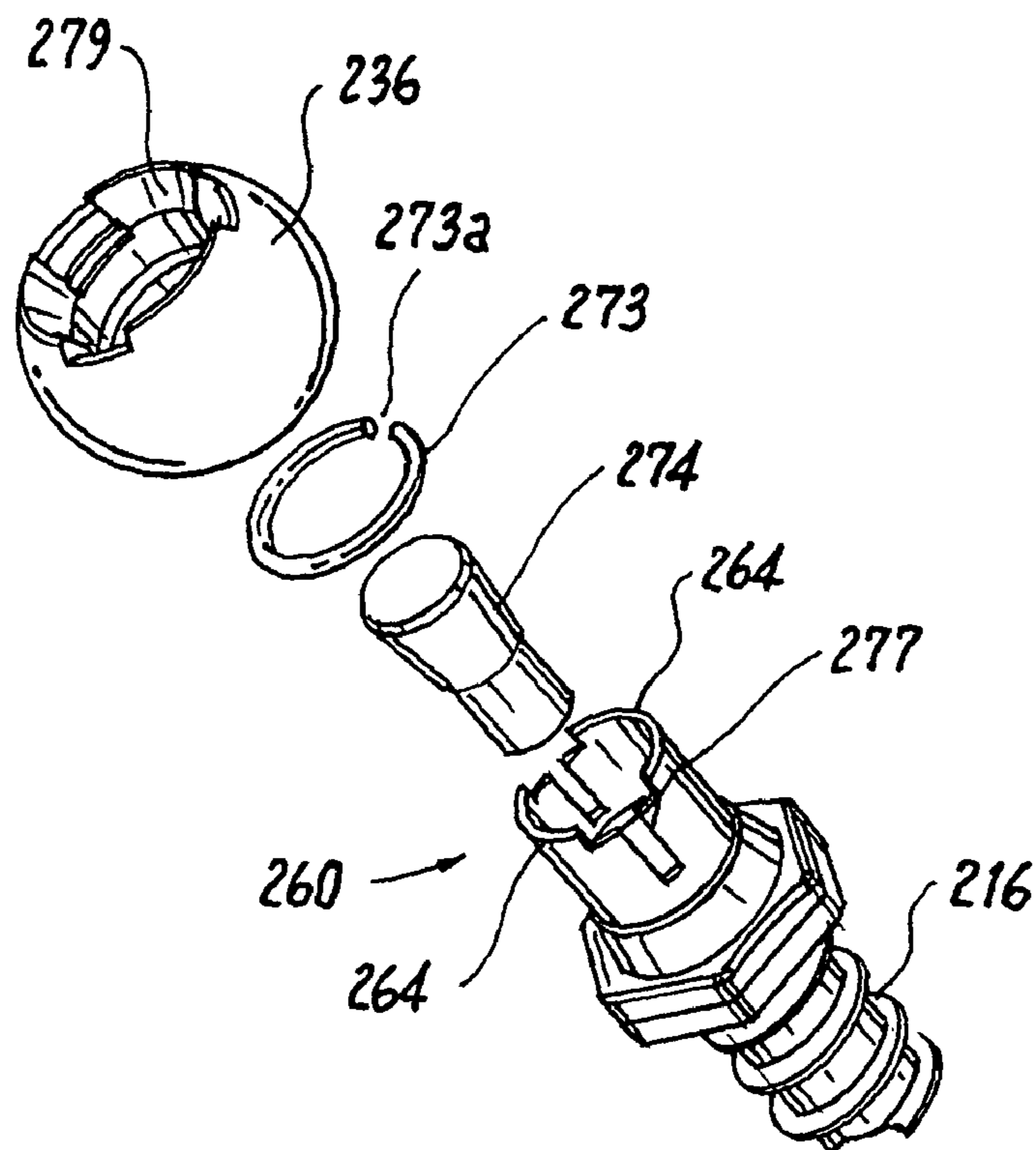


FIG. 24b

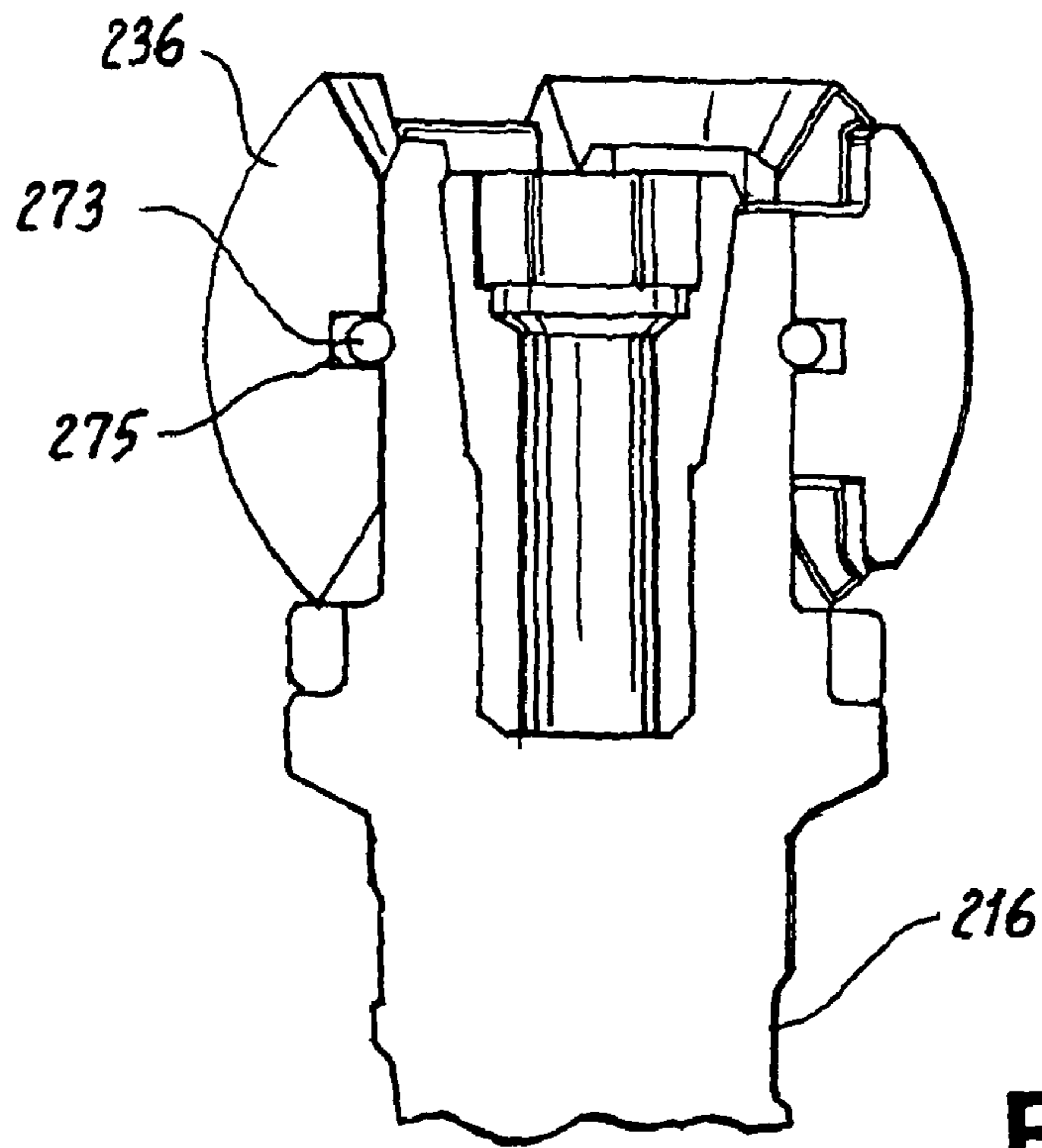


FIG. 24c

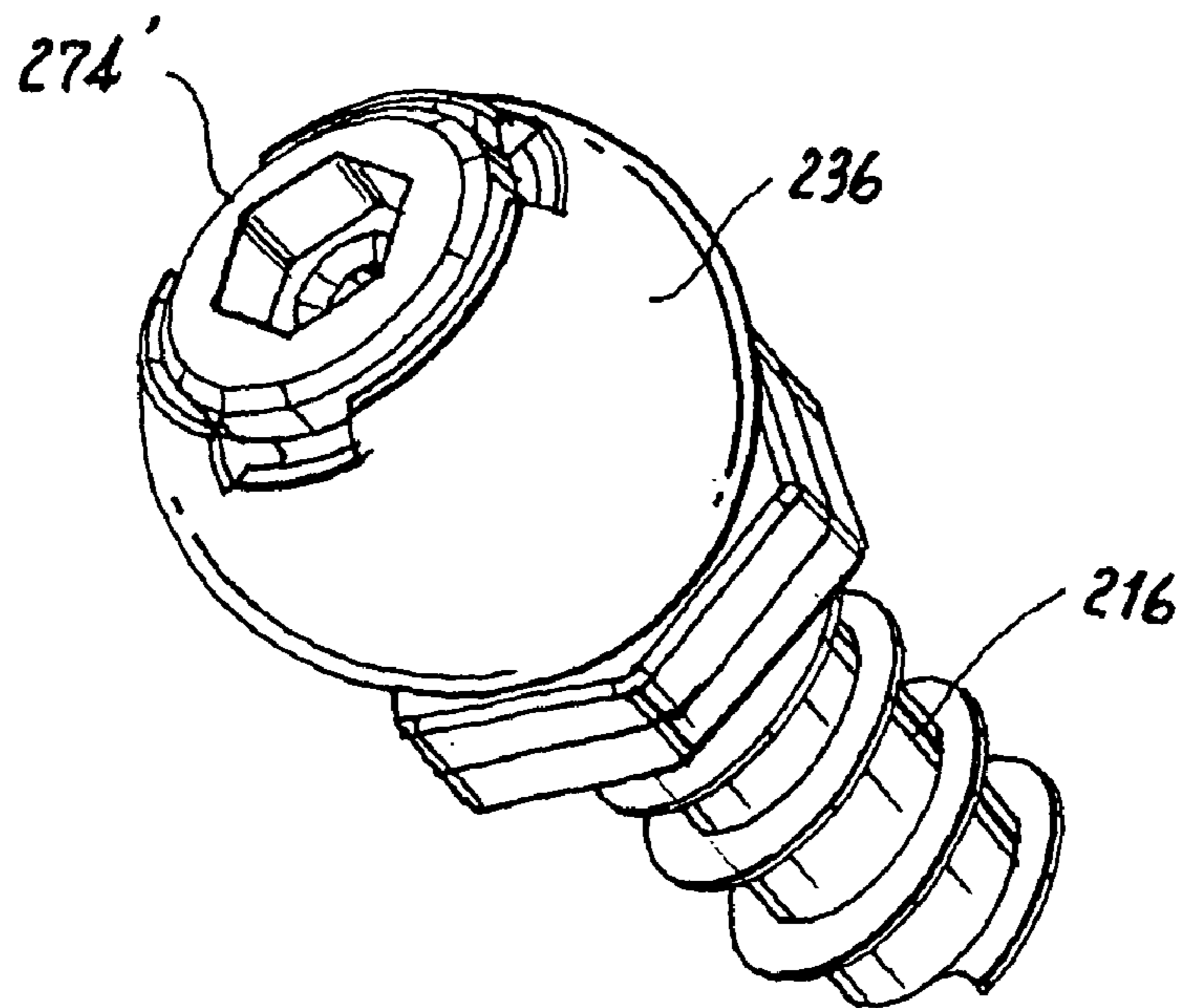


FIG. 25a

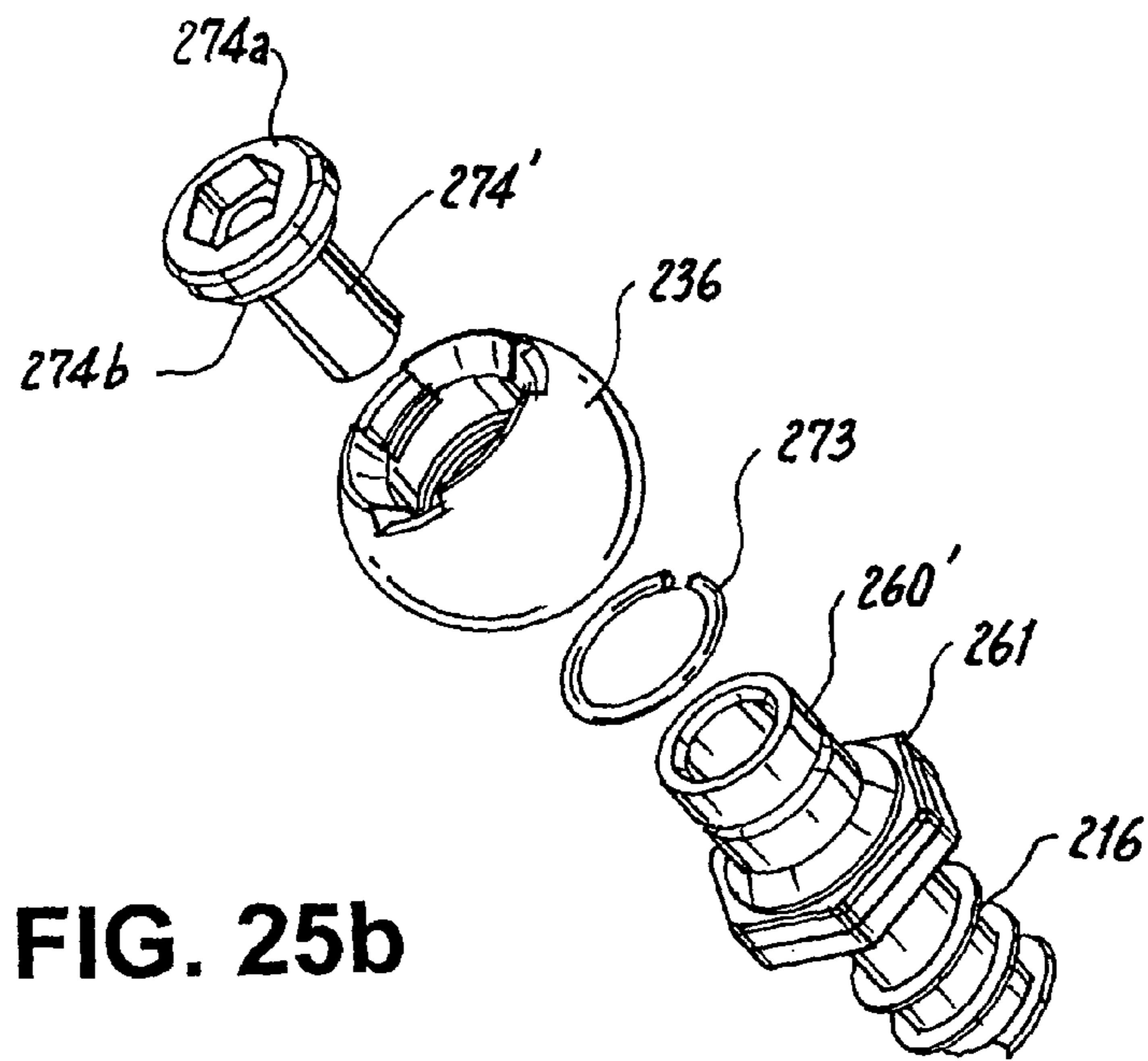


FIG. 25b

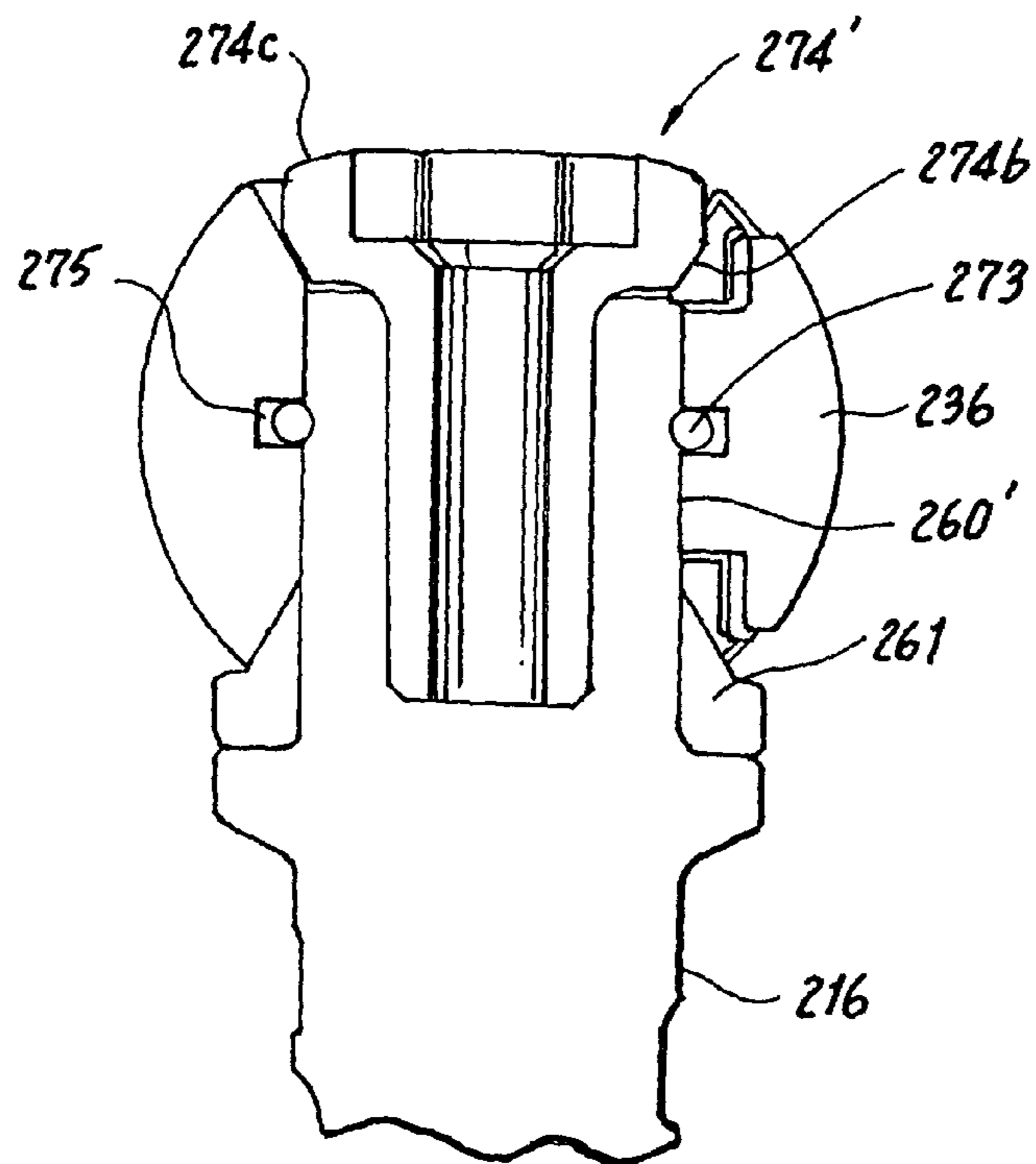


FIG. 25c

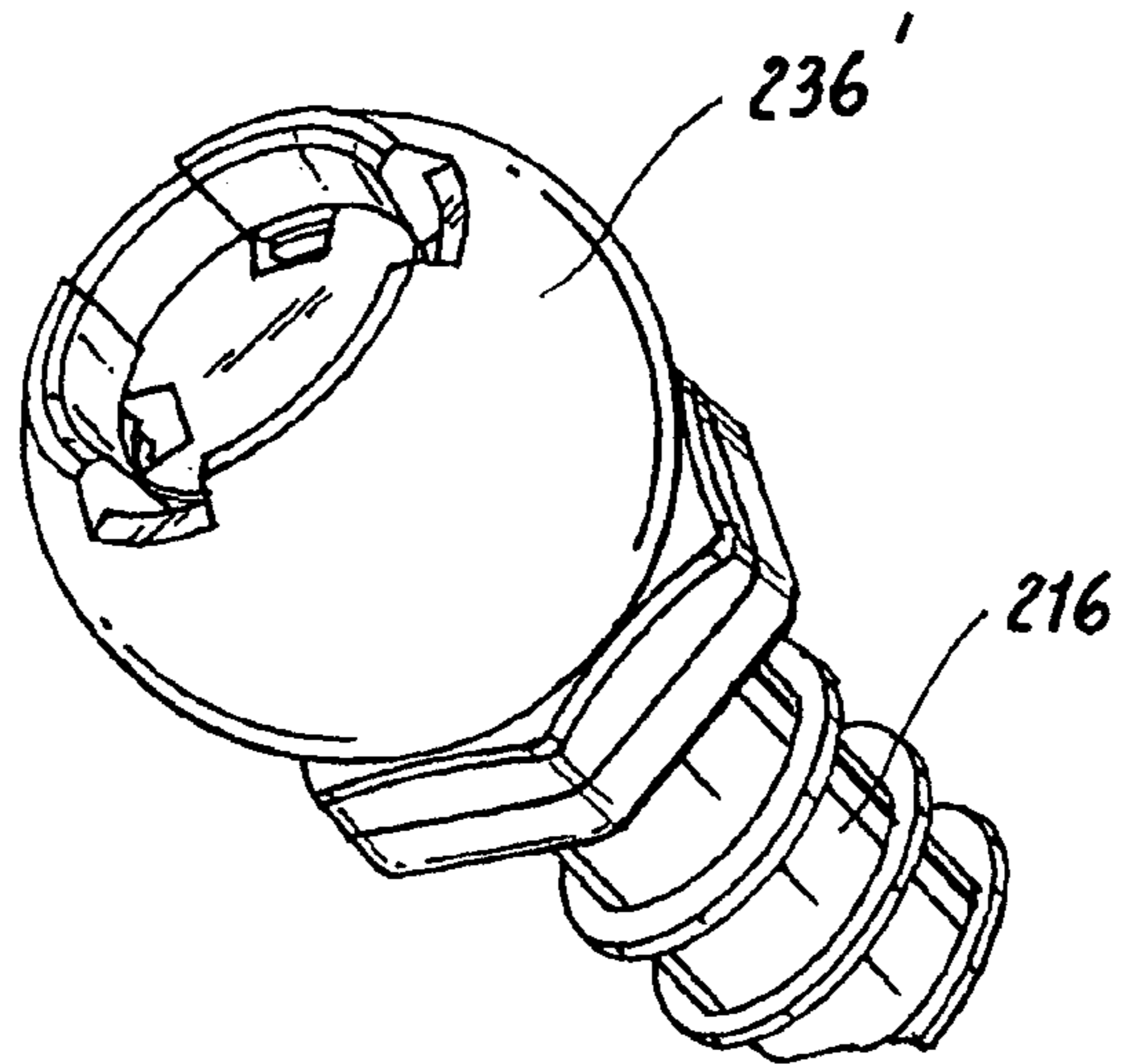


FIG. 26a

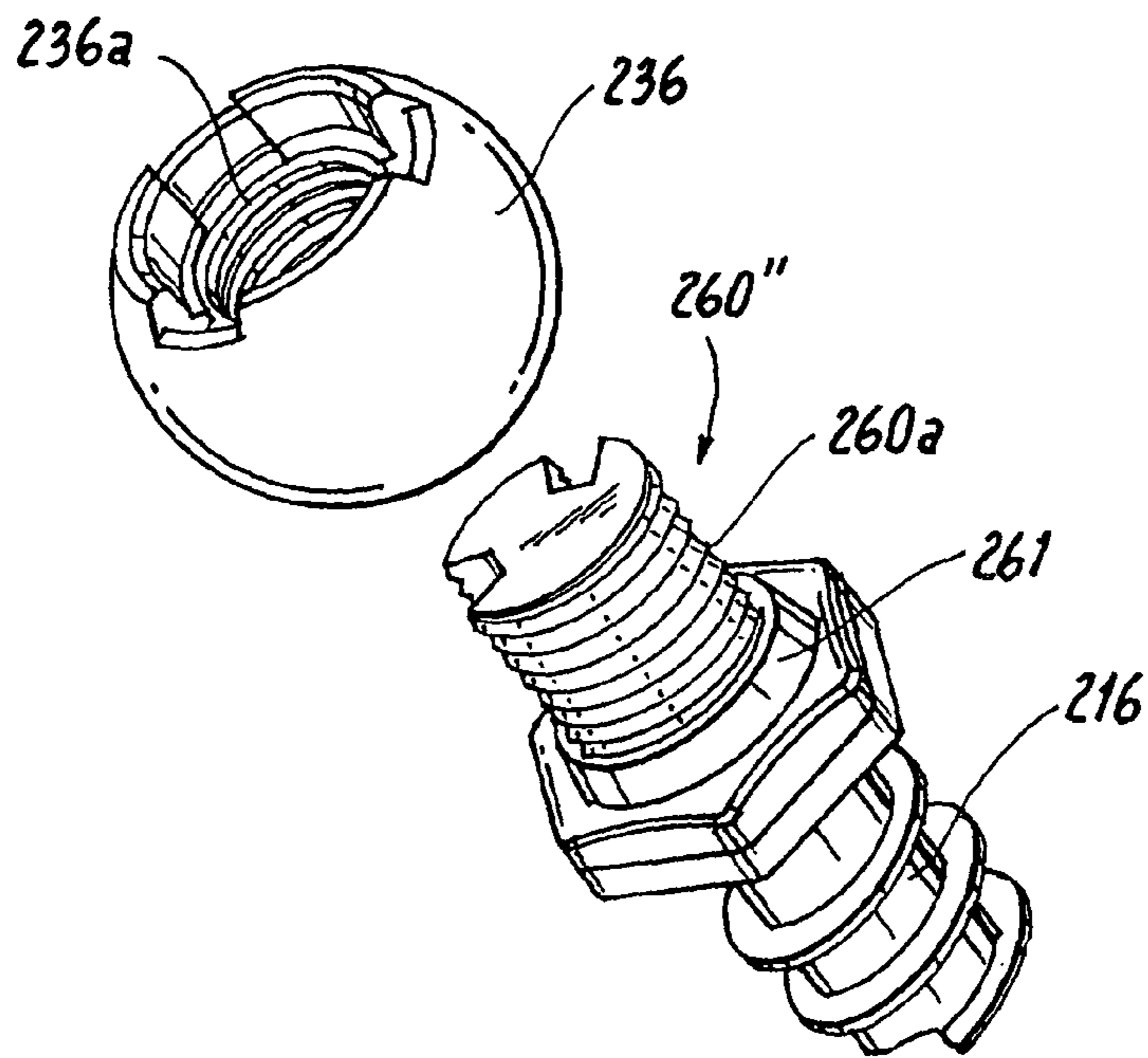


FIG. 26b

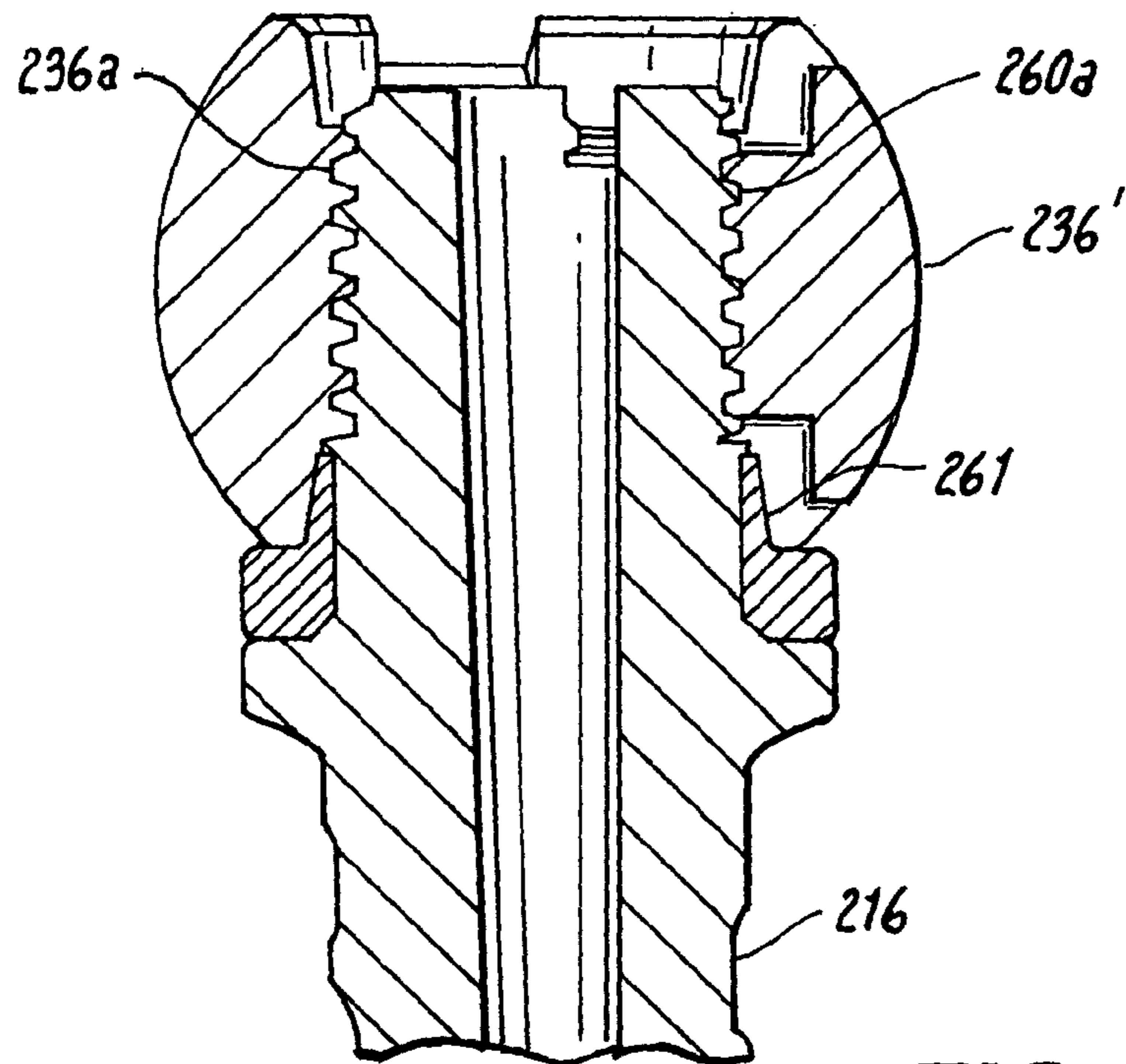


FIG. 26c

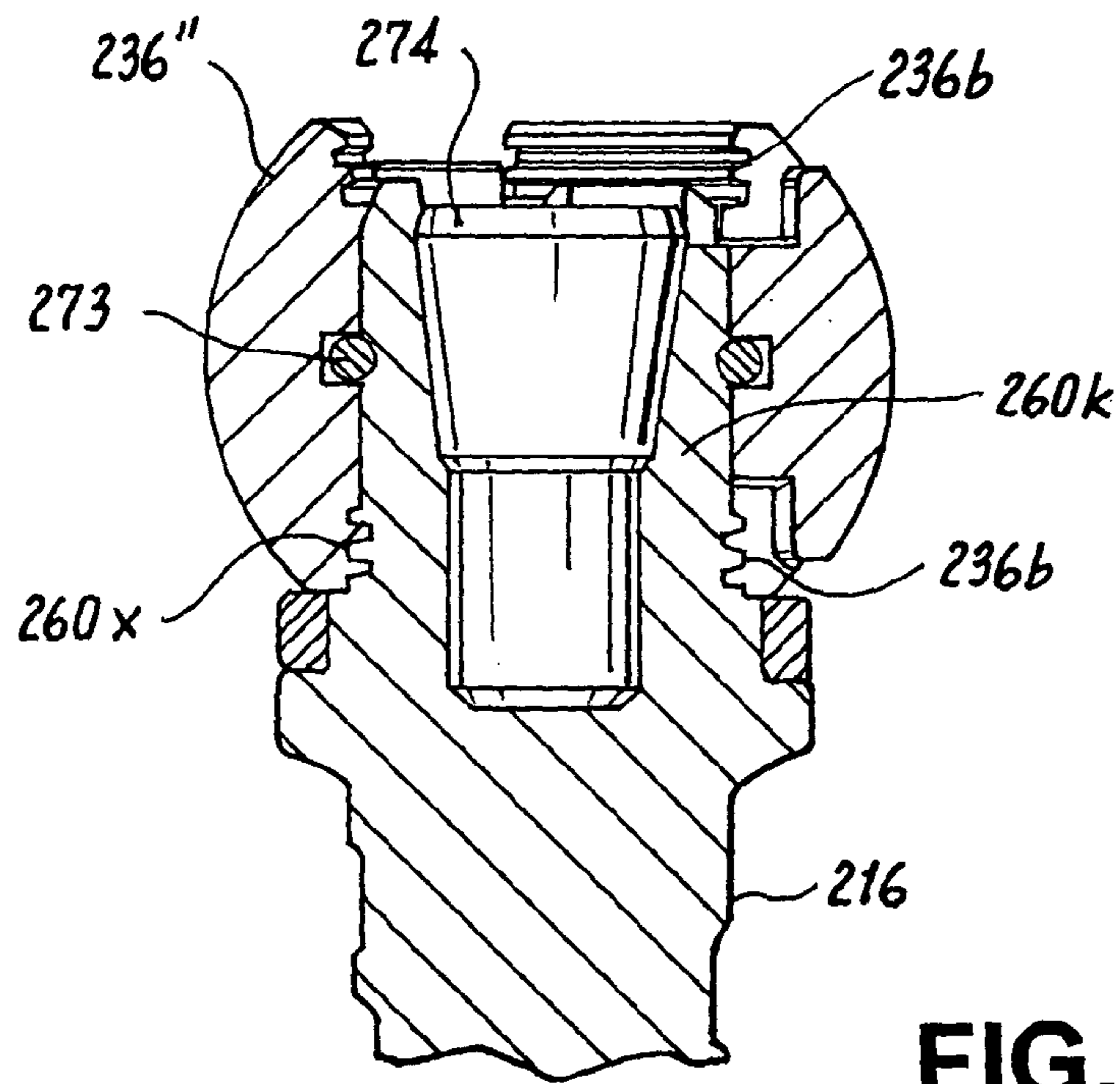
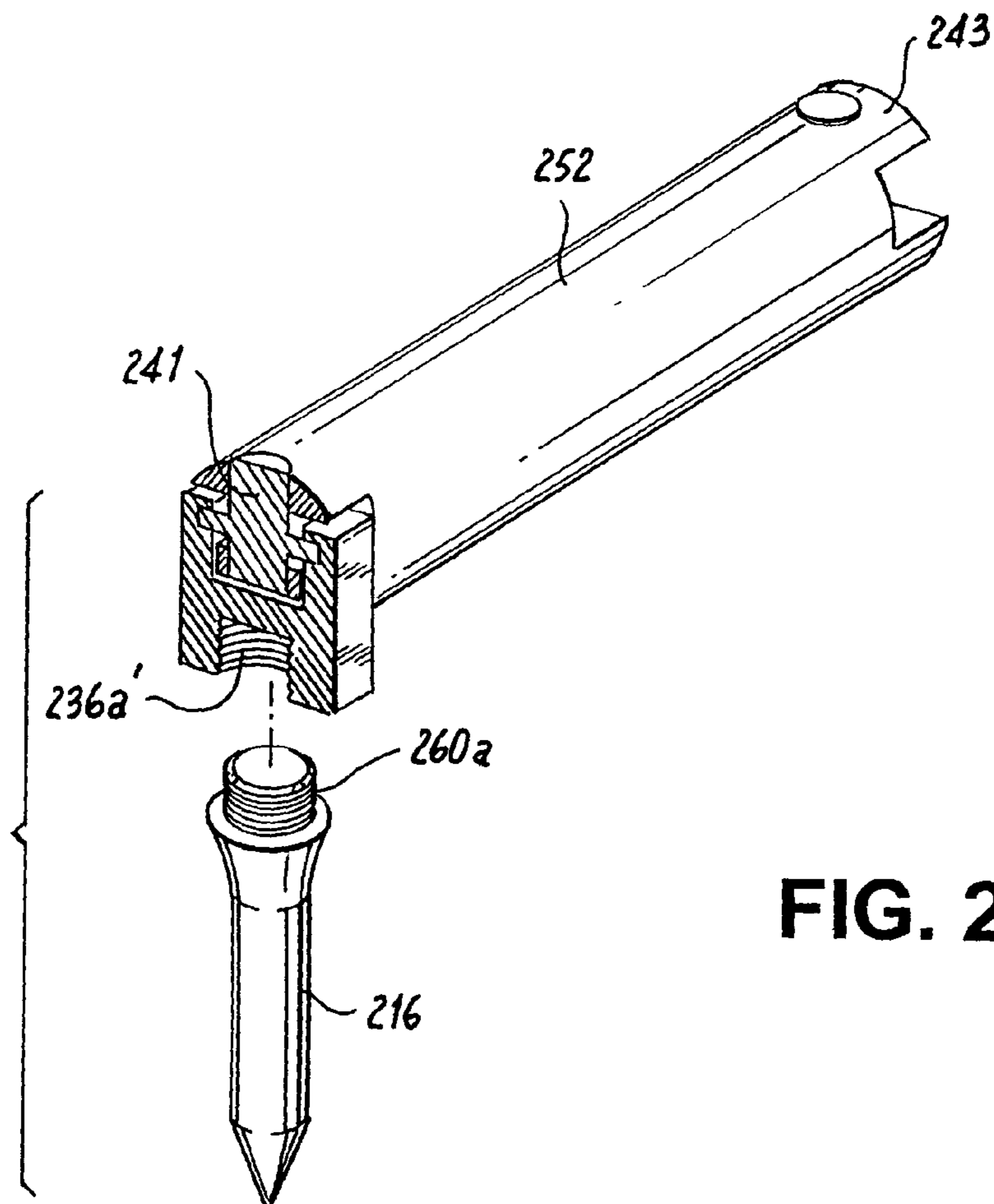
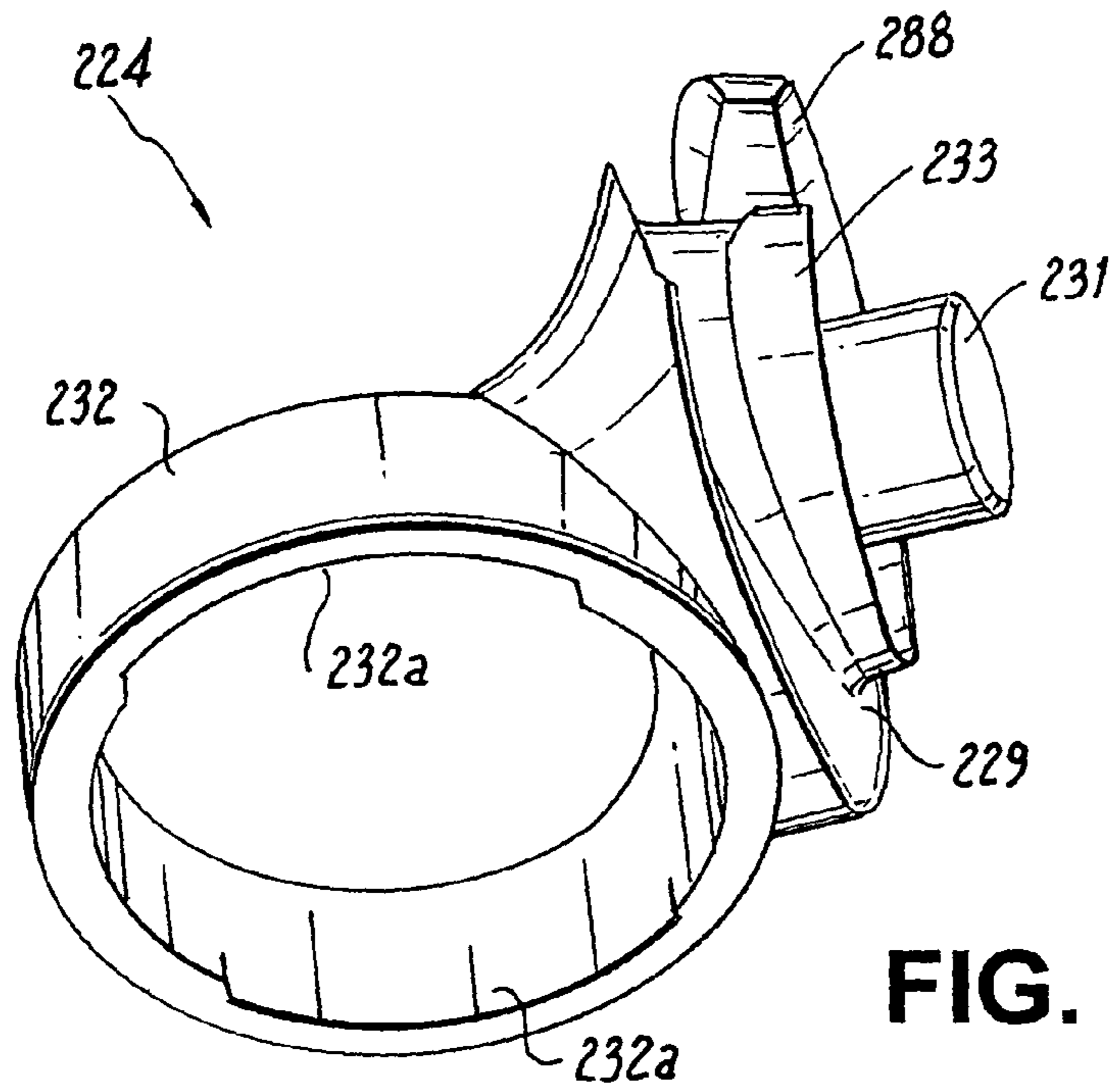


FIG. 27



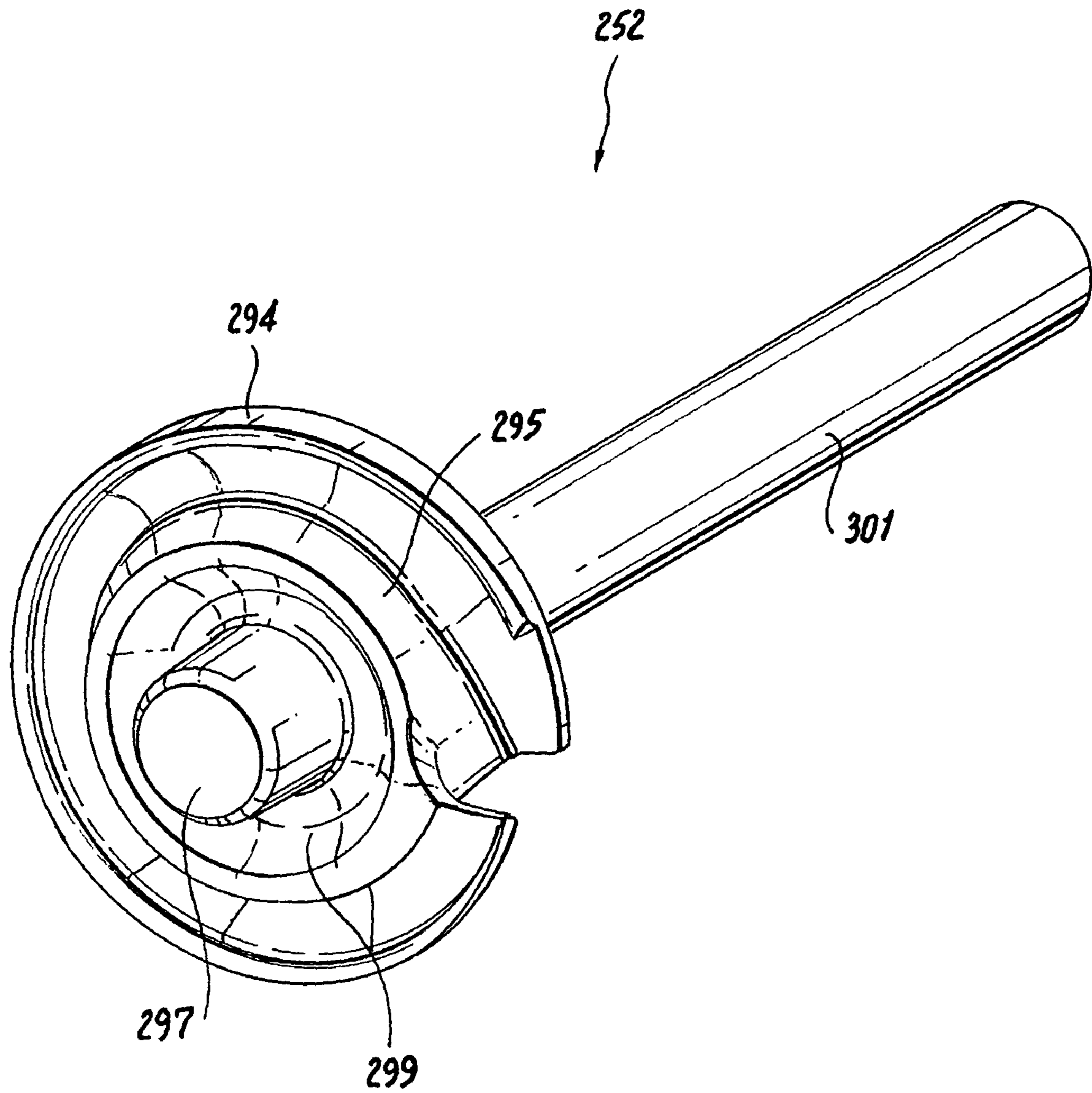


FIG. 30

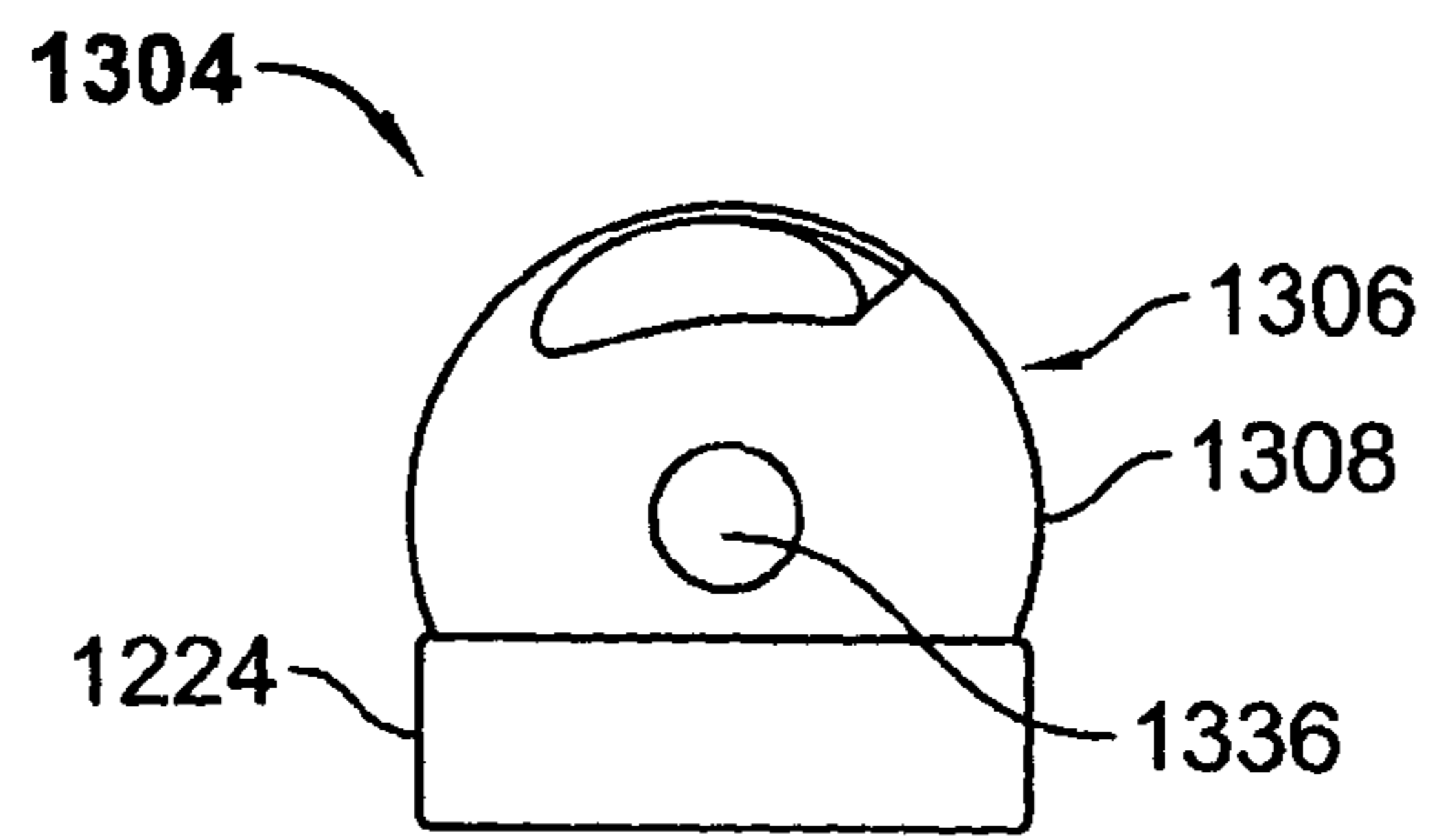


FIG. 31

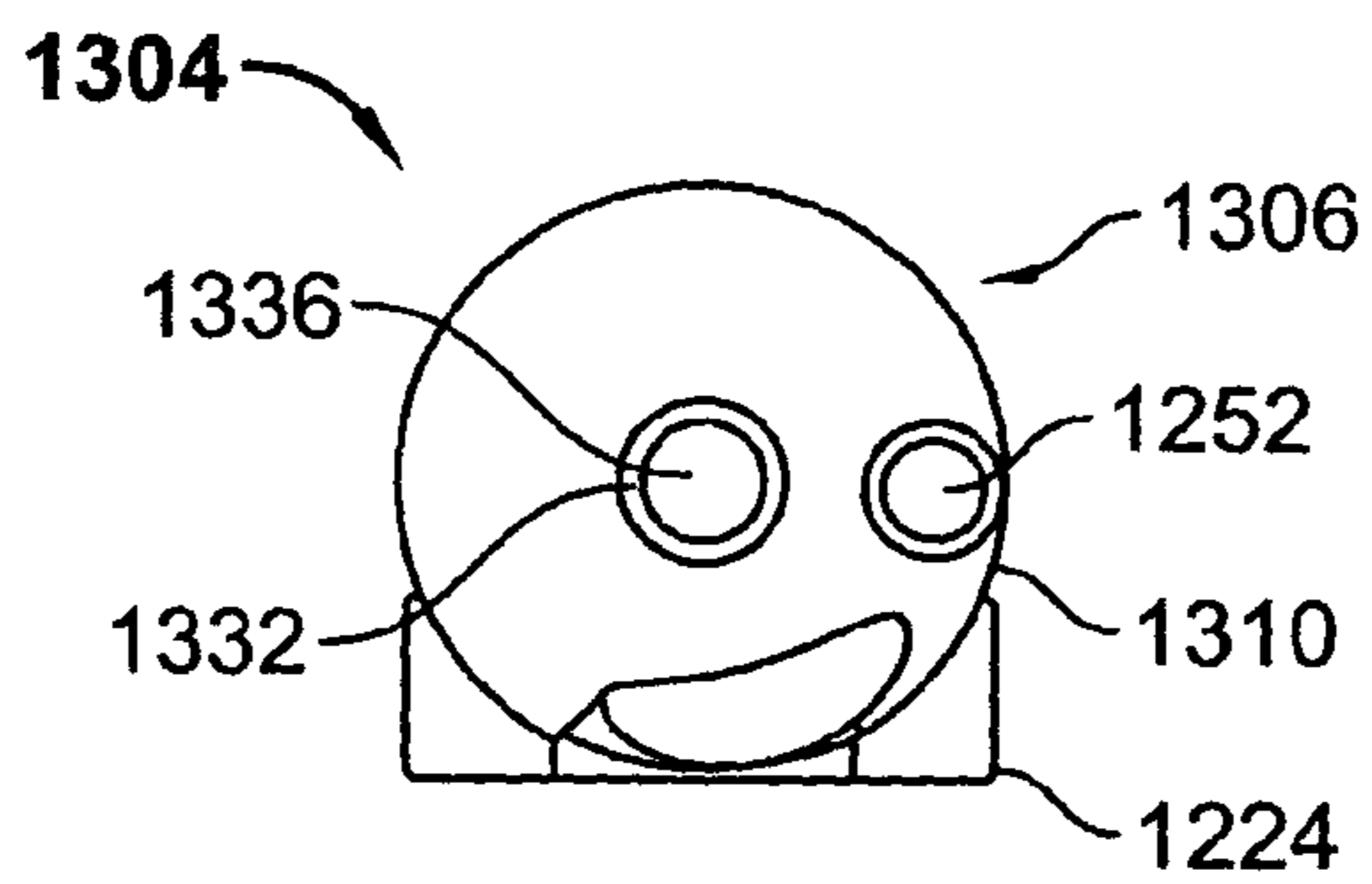


FIG. 32

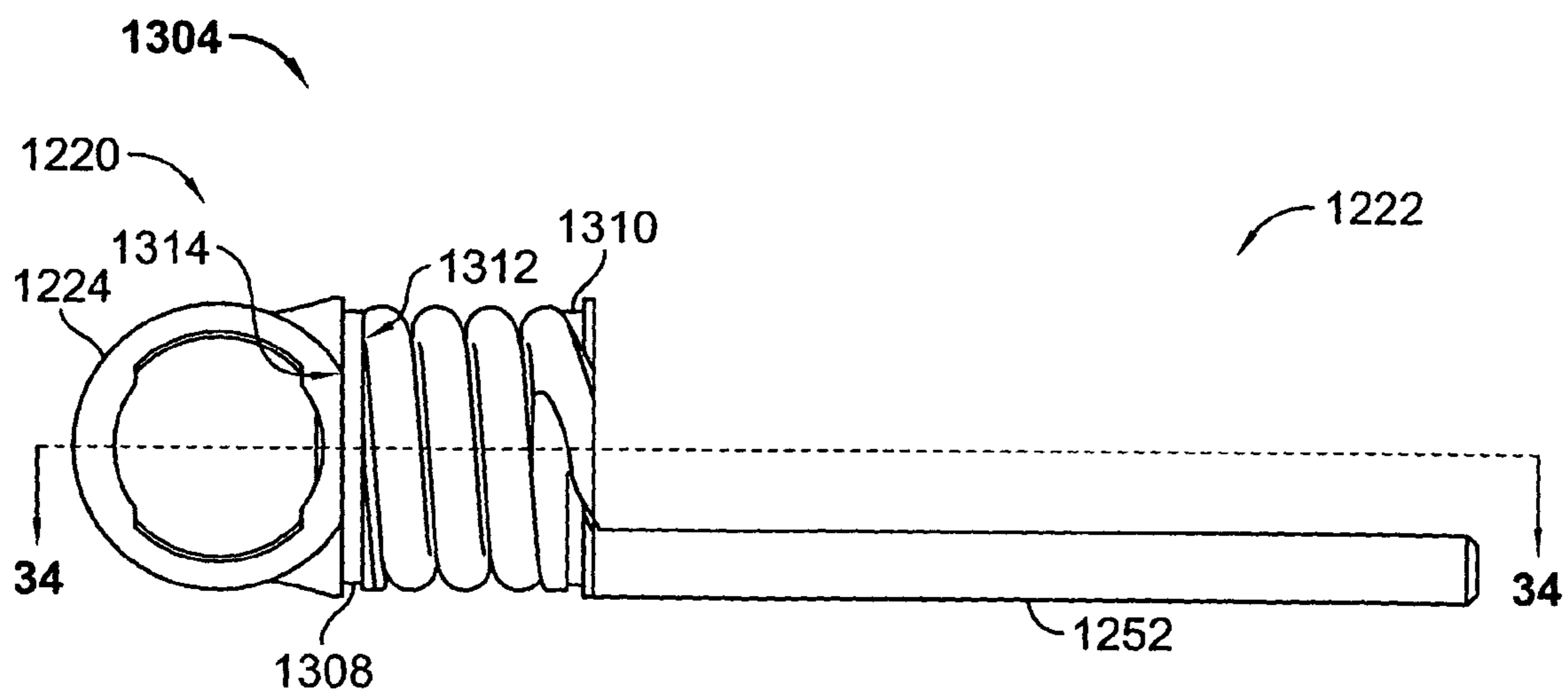


FIG. 33

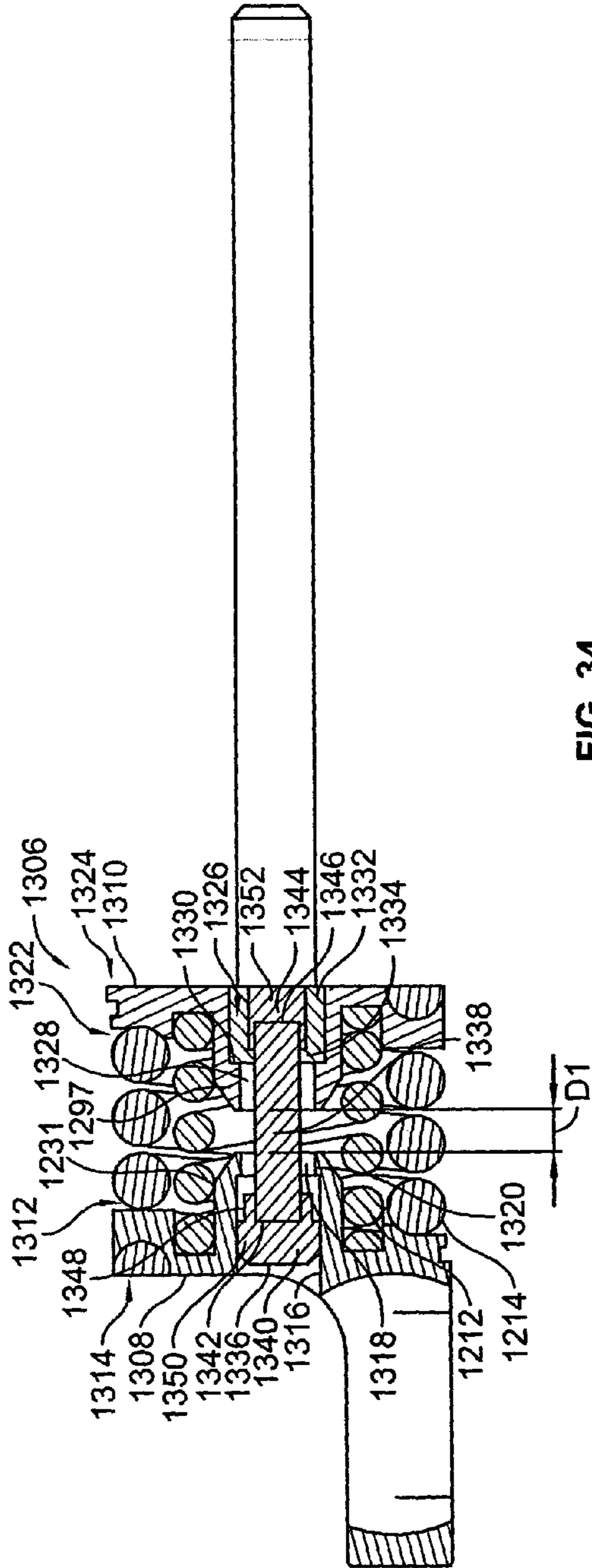


FIG. 34

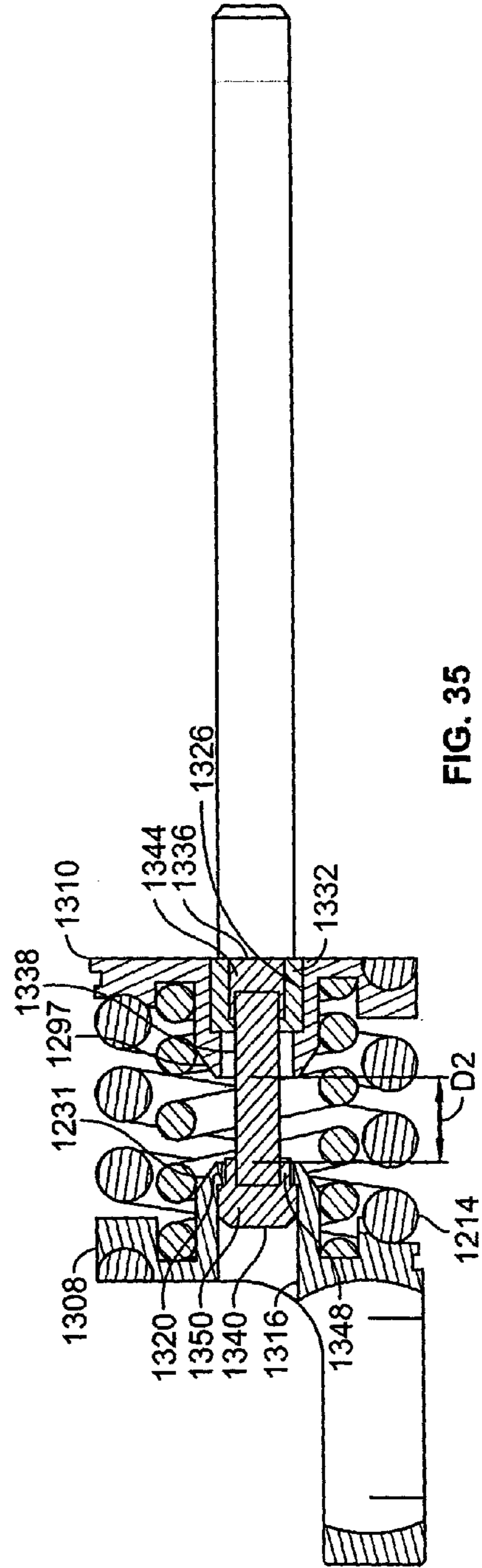


FIG. 35

DYNAMIC SPINE STABILIZATION DEVICE WITH TRAVEL-LIMITING FUNCTIONALITY

BACKGROUND OF THE INVENTION

1. Technical Field

The present disclosure relates to advantageous methods and apparatus for spinal stabilization. More particularly, the present disclosure relates to methods and apparatus for providing dynamic stabilization to the spine so as to provide clinically efficacious results and to such methods/apparatus that include travel-limiting functionality.

2. Background Art

Low back pain is one of the most expensive diseases afflicting industrialized societies. With the exception of the common cold, it accounts for more doctor visits than any other ailment. The spectrum of low back pain is wide, ranging from periods of intense disabling pain which resolve to varying degrees of chronic pain. The conservative treatments available for lower back pain include: cold packs, physical therapy, narcotics, steroids and chiropractic maneuvers. Once a patient has exhausted all conservative therapy, the surgical options generally range from micro discectomy, a relatively minor procedure to relieve pressure on the nerve root and spinal cord, to fusion, which takes away spinal motion at the level of pain.

Each year, over 200,000 patients undergo lumbar fusion surgery in the United States. While fusion is effective about seventy percent of the time, there are consequences even to these successful procedures, including a reduced range of motion and an increased load transfer to adjacent levels of the spine, which may accelerate degeneration at those levels. Further, a significant number of back-pain patients, estimated to exceed seven million in the U.S., simply endure chronic low-back pain, rather than risk procedures that may not be appropriate or effective in alleviating their symptoms.

New treatment modalities, collectively called motion preservation devices, are currently being developed to address these limitations. Some promising therapies are in the form of nucleus, disc or facet replacements. Other motion preservation devices provide dynamic internal stabilization of the injured and/or degenerated spine, e.g., the Dynesys stabilization system (Zimmer, Inc.; Warsaw, Ind.) and the Graf Ligament. A major goal of this concept is the stabilization of the spine to prevent pain while preserving near normal spinal function.

To provide dynamic internal spinal stabilization, motion preservation devices may advantageously include stabilizing members that exhibit multiple degrees of freedom and commonly include active force-absorbing/force-generating structures. Such structures may include one or more resilient elements, e.g., torsion springs and/or wire coil springs, designed and deployed so as to contribute strength and flexibility to the overall device. While the flexibility afforded by such resilient elements is plainly critical to the effectiveness of the respective devices of which they form a part, the elevated force levels associated with the use of such resilient elements can result in such resilient elements developing significant levels of internal stress and/or responding to such stress by undergoing significant deformation, either or both of which may be undesirable depending on the particular device or surgical application.

With the foregoing in mind, those skilled in the art will understand that a need exists for devices, systems and/or methods for motion-preserving spinal stabilization devices and systems having stabilizing members with resilient elements, the internal stress levels and deformation response

characteristics of which are appropriately controlled and managed. These and other needs are satisfied by the devices, systems and methods disclosed herein.

SUMMARY OF THE PRESENT DISCLOSURE

According to the present disclosure, advantageous devices, systems and methods for spinal stabilization are provided. According to exemplary embodiments of the present disclosure, the disclosed devices, systems and methods include a dynamic stabilization element and a stabilization member junction that promotes reliable and efficacious spinal stabilization. The disclosed stabilization member junction is generally formed with respect to attachment members that are mounted or mountable with respect to a pedicle screw. In further implementations of the present disclosure, advantageous devices, systems and methods for spinal stabilization are provided that include a dynamic stabilization member that includes and/or interacts with a travel-limiting element/functionality.

According to exemplary embodiments of the present disclosure, a stabilization member includes a first structural member mountable with respect to a pedicle screw, a second structural member adjacent the first structural member and that is able to move with respect to the first structural member, and a resilient element disposed between and mounted with respect to the first and second structural members. The resilient element, e.g., one or more coil springs, is generally able to elongate as the second structural element moves and/or rotates with respect to the first structural member, e.g., the second structural element moves away from the first structural element. A travel-limiting structure is advantageously provided in conjunction with the foregoing assembly.

The disclosed travel-limiting structure is typically disposed between the first and second structural members, and acts to define and/or impose a maximum distance by which the first and second structural member may be separated, i.e., travel with respect to each other. In exemplary embodiments, the travel-limiting structure includes an elongate element disposed between the first and second structural members. Such elongate element can be axially inextensible and/or of a fixed axial length. While such elongate element may be laterally flexible with respect to some particularly advantageous exemplary embodiments (e.g., the elongate element may take the form, in whole or in part, of a metallic wire-rope cable), the elongate element can alternatively be laterally stiff and inflexible (e.g., a metallic bar or pin). Of note, the travel-limiting structure may also combine the foregoing functional properties, e.g., it may be laterally flexible in part and laterally inflexible in part. In further exemplary embodiments of the present disclosure, the second structural member may be both axially and rotationally movable relative to the first structural member.

Thus, according to an exemplary implementation of the disclosed travel-limiting functionality, the first and second structural members engage opposite ends of the elongate element when they are separated by the maximum allowable separation distance. Such maximum allowable separation distance is thus predefined by the structural interaction between the first/second structural members and the elongate element. Through selection of the physical properties of the foregoing components, a spinal stabilization device/system having a desired maximum relative travel may be advantageously designed/engineered. According to further embodiments of the present disclosure, such maximum relative travel parameter may be adjustable, e.g., through provision of an

adjustment feature with respect to the structural interaction between the first and/or second structural member and the elongate element.

In exemplary embodiments of the present disclosure, the travel-limiting structure may further include first and second terminations at respective opposite ends of the elongate element which are configured and dimensioned to be axially engaged by the respective first and second structural elements. Moreover, the disclosed resilient element may be disposed against a first end of one of the structural members, the corresponding termination may be disposed adjacent a second end of that structural member, and the elongate element may extend therethrough. In this way, the elongate element may be movable with respect to the structural member. In further exemplary embodiments, a pocket may be formed in the second end of the structural member and a lip formed at the bottom of the pocket adjacent the aperture that extends therethrough. The corresponding termination may include a shoulder disposed within the pocket that is configured and dimensioned to be axially movable within the pocket to a depth of the lip. A cylindrical collar may also be provided that is configured and dimensioned to lodge in the aperture to align the termination with the structural.

According to still further exemplary embodiments of the present disclosure, the opposite termination of the travel-limiting structure may be affixed to the other/second structural member in a manner which prevents the elongate element from axial travel relative to the other/second structural member. In some such embodiments, the resilient element may be disposed against a first end of the other structural member, with the associated termination being disposed adjacent a second end of the other/second structural member opposite the first end thereof. The elongate element may extend through an aperture formed in the other/second structural member. In some such embodiments, a pocket is formed in the second end of the other structural member, and a lip is formed at the bottom of the pocket adjacent the aperture that extends therethrough. The associated termination may include a cylindrical collar lodged within the pocket no deeper than to a depth of the lip so as to axially align the other termination with such structural member. Moreover, the second structural member may additionally include a sleeve insert in the pocket into which the other termination is inserted, such sleeve functioning to enhance alignment and durability of the junction.

Also according to the present disclosure, an apparatus, device and/or system is provided in which the following elements/components are provided in combination: a first structural member, a second structural member, a wire coil spring disposed and mounted between respective first ends of the structural members, and a travel-limiting structure for limiting a distance by which the first and second structural elements may be separated. The travel-limiting structure typically includes an elongate element having first and second ends, a first termination at the first end of the elongate element, and a second termination at the second end of the elongate element. The assembly/subassembly associated with such combination advantageously functions to limit the relative travel of the first structural element and the second structural element.

The disclosed assembly/subassembly is advantageously employed in conjunction with a dynamic spinal stabilizing system that includes one or more stabilizing member(s). Thus, the foregoing assemblies/subassemblies and associated stabilizing member(s) are typically employed as part of a

spinal stabilization system that may advantageously include one or more of the following structural and/or functional attributes:

The outer resilient member or spring of the stabilizing member is shielded from undue stress and/or undue extension by the limiting structure.

Depending on an overall length of the cable between the termination blocks, the stabilizing member can be employed to limit a linear and/or angular distance between the structural members/spring caps to any desired dimension.

The dimensional flexibility of the limiting structure can be used to match the needs and/or physical characteristics of a particular patient.

In another advantage stemming from such flexibility, the stabilization member can be tuned in relation to adjacent stabilization members and/or adjacent intervertebral segments in order to distribute the burden of spinal movement across multiple adjacent portions of the spine by inducing and/or forcing incrementally greater involvement of, or contributions from, adjacent intervertebral segments with respect to global spinal flexion, extension, or twist.

The stabilization member can be used to permit a small degree of intervertebral flexibility in the spine of a surgical patient whose condition might otherwise call for the employment of a spinal fusion technique.

Advantageous spine stabilization devices, systems and methods may incorporate one or more of the foregoing structural and/or functional attributes. Thus, it is contemplated that a system, device and/or method may utilize only one of the advantageous structures/functions set forth above, a plurality of the advantageous structures/functions described herein, or all of the foregoing structures/functions, without departing from the spirit or scope of the present disclosure. Stated differently, each of the structures and functions described herein is believed to offer benefits, e.g., clinical advantages to clinicians and/or patients, whether used alone or in combination with others of the disclosed structures/functions.

Additional advantageous features and functions associated with the devices, systems and methods of the present disclosure will be apparent to persons skilled in the art from the detailed description which follows, particularly when read in conjunction with the figures appended hereto. Such additional features and functions, including the structural and mechanistic characteristics associated therewith, are expressly encompassed within the scope of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

To assist those of ordinary skill in the art in making and using the disclosed devices, systems and methods for spinal stabilization and other applications, reference is made to the appended figures wherein:

FIG. 1 is a Moment-Rotation curve for a spinal segment (intact and injured), showing relatively low spinal stiffness within the neutral zone;

FIG. 2 is a schematic representation of a spinal segment in conjunction with a Moment-Rotation curve for a spinal segment, showing relatively low spinal stiffness within the neutral zone;

FIG. 3a is a schematic representation of an exemplary device/system according to the present disclosure in conjunction with a Force-Displacement curve, demonstrating increased resistance provided within the central zone of a dynamic spine stabilizer according to the present disclosure;

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FIG. 3*b* is a Force-Displacement curve demonstrating a change in profile achieved through replacement of springs according to an exemplary embodiment of the present disclosure;

FIG. 3*c* is a posterior or dorsal view of the spine with a pair of exemplary stabilizers secured thereto;

FIG. 3*d* is a lateral or side view showing an exemplary stabilizer according to the present disclosure in tension;

FIG. 3*e* is a lateral or side view showing an exemplary stabilizer according to the present disclosure in compression;

FIG. 4 is a schematic representation of an exemplary dynamic spine stabilizer according to the present disclosure;

FIG. 5 is a schematic representation of an alternate exemplary embodiment of a dynamic spine stabilizer in accordance with one aspect of the present disclosure;

FIG. 6 is a Moment-Rotation curve demonstrating the manner in which an exemplary dynamic spine stabilizer according to the present disclosure assists spinal stabilization;

FIGS. 7*a* and 7*b* are, respectively, a free body diagram of an exemplary dynamic stabilizer according to the present disclosure and a diagram representing the central zone of such exemplary stabilizer;

FIG. 8 is an exploded view of an exemplary dynamic spine stabilization system in accordance with an embodiment of the present disclosure;

FIG. 9 is a perspective view of the exemplary dynamic spine stabilization system shown in FIG. 8;

FIGS. 10 and 11 are perspective views showing exemplary attachment members for use with dynamic spine stabilizations of the present disclosure;

FIG. 12 is a schematic representation showing a guidewire assembly technique in accordance with an exemplary implementation of the spine stabilization techniques of the present disclosure;

FIG. 13 is a schematic side view of a pair of pedicle screws according to an exemplary embodiment of the present disclosure;

FIG. 14 is a side view of a pair of pedicle screws in combination with guidewire assemblies according to an exemplary embodiment of the present disclosure;

FIG. 15*a* is a perspective view of an attachment member that is adapted to facilitate alignment with elongated member(s), e.g., rod(s), according to exemplary embodiments of the present disclosure;

FIG. 15*b* is a side view of a spherical element for use in an attachment member according to an exemplary embodiment of the present disclosure;

FIG. 16 is a top view of a pair of single level spinal stabilization systems according to an exemplary embodiment of the present disclosure;

FIG. 17 is an illustrative Force-Displacement curve for an exemplary dynamic spine stabilization system according to the present disclosure;

FIG. 18 is a schematic top view of an exemplary multiple level, dynamic spine stabilization system in accordance with an implementation of the present disclosure;

FIG. 19 is a schematic, exploded side view of a portion of the exemplary dynamic spine stabilization system of FIG. 18;

FIG. 20 is a schematic side view of an aspect of the exemplary dynamic spine stabilization system of FIG. 18;

FIG. 21 is a perspective view of the exemplary multiple level, dynamic spine stabilization system of FIGS. 18 to 20;

FIG. 22 is a further perspective view of the exemplary multiple level, dynamic spine stabilization system of FIG. 19;

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FIG. 23 is a side view of exemplary portions of a pedicle screw/ball joint subassembly (partially exploded) according to the present disclosure;

FIGS. 24*a*, 24*b* and 24*c* are views of an alternative collet-based mechanism according to the present disclosure;

FIGS. 25*a*, 25*b* and 25*c* are views of a non-spreading collet-based mechanism according to the present disclosure;

FIGS. 26*a*, 26*b* and 26*c* are views of a further alternative mechanism for mounting a ball/sphere relative to a pedicle screw according to the present disclosure;

FIG. 27 is a cross-sectional side view an additional alternative mechanism for mounting a ball/sphere relative to a pedicle screw according to the present disclosure;

FIG. 28 is a perspective view of an exemplary socket member and spring cap according to an exemplary embodiment of the present disclosure;

FIG. 29 is an exploded view of an alternative dynamic junction between a pedicle screw and accessory component(s) according to the present disclosure;

FIG. 30 is a perspective view of a spring cap rod according to an exemplary embodiment of the present disclosure;

FIGS. 31-33 are first and second end views and a side view of components associated with an exemplary stabilization system according to the present disclosure;

FIG. 34 is a cross-sectional view of aspects of an exemplary stabilization system assembled from the components of FIGS. 31-33; and

FIG. 35 is a cross-sectional view of the assembly of FIG. 34 in which relative travel between components thereof is reflected.

DESCRIPTION OF EXEMPLARY EMBODIMENTS

The present disclosure provides advantageous devices, systems and methods for spinal stabilization and/or alternative surgical implant applications. More particularly, the present disclosure provides devices, systems and methods that deliver dynamic stabilization to the spine so as to provide clinically efficacious results. The exemplary embodiments disclosed herein are illustrative of the advantageous spine stabilization systems and surgical implants of the present disclosure, and methods/techniques for implementation thereof. It should be understood, however, that the disclosed embodiments are merely exemplary of the present invention, which may be embodied in various forms. Therefore, the details disclosed herein with reference to exemplary dynamic spinal stabilization systems and associated methods/techniques are not to be interpreted as limiting, but merely as the basis for teaching one skilled in the art how to make and/or use the advantageous dynamic spinal stabilization systems and alternative surgical implants of the present disclosure.

With reference to FIGS. 2, 3*a-e* and 4, an exemplary method and apparatus for spinal stabilization are disclosed. Although the description which follows is primarily directed to spinal stabilization, it is expressly contemplated that the disclosed methods and apparatus may be advantageously employed in alternative surgical applications, e.g., any long bone application. Thus, throughout the detailed disclosure which follows, it is to be understood that references and teachings with respect to spinal stabilization are merely illustrative and that the disclosed systems, devices and methods find application in a multitude of a surgical/anatomical settings, including specifically long bone applications involving the femur, tibia, fibula, ulna, and/or humerus.

In accordance with an exemplary embodiment of the present disclosure, the spinal stabilization method is achieved

by securing an internal dynamic spine stabilizing member **10** between adjacent vertebrae **12**, **14**, thereby providing mechanical assistance in the form of elastic resistance to the region of the spine to which the dynamic spine stabilizing member **10** is attached. The elastic resistance is applied as a function of displacement such that greater stiffness, i.e., greater incremental resistance, is provided while the spine is in its neutral zone and lesser mechanical stiffness, i.e., lesser incremental resistance, is provided while the spine bends beyond its neutral zone. Although the term elastic resistance is generally used throughout the body of the present specification, other forms of resistance may be employed without departing from the spirit of the present invention.

As those skilled in the art will certainly appreciate, and as mentioned above, the “neutral zone” is understood to refer to a region of low spinal stiffness or the toe-region of the Moment-Rotation curve of the spinal segment (see FIG. 2). That is, the neutral zone may be considered to refer to a region of laxity around the neutral resting position of a spinal segment where there is minimal resistance to inter-vertebral motion. The range of the neutral zone is considered to be of major significance in determining spinal stability. Panjabi, M. M. “The stabilizing system of the spine. Part II. Neutral zone and instability hypothesis.” *J Spinal Disorders* 1992; 5(4): 390-397.

In fact, Dr. Panjabi (a presently named inventor) has previously described the load displacement curve associated with spinal stability through the use of a “ball in a bowl” analogy. According to this analogy, the shape of the bowl indicates spinal stability. A deeper bowl represents a more stable spine, while a more shallow bowl represents a less stable spine. Dr. Panjabi previously hypothesized that for someone without spinal injury there is a normal neutral zone (that part of the range of motion where there is minimal resistance to inter-vertebral motion) with a normal range of motion and, in turn, no spinal pain. In this instance, the bowl is not too deep nor too shallow. However, when an injury occurs to an anatomical structure associated with the spine, the neutral zone of the spinal column increases and “the ball” moves freely over a larger distance. By the noted analogy, the bowl would be shallower and the ball less stable; consequently, pain would result from the enlarged neutral zone.

In general, pedicle screws **16**, **18** are used to attach the dynamic spine stabilizing member **10** to the vertebrae **12**, **14** of the spine using well-tolerated and familiar surgical procedures known to those skilled in the art. The pedicle screws **16**, **18** in combination with a dynamic spine stabilizing member **10** comprise a stabilizing system **11**. In accordance with an exemplary embodiment, and as those skilled in the art will certainly appreciate, paired stabilizing systems **11** are commonly used to balance the loads applied to the spine (see FIG. 3c). The dynamic spine stabilizing members **10** assist the compromised (injured and/or degenerated) spine of a back-pain patient, and help her/him perform daily activities. The dynamic spine stabilizing member **10** does so as part of stabilizing system **11** by providing controlled resistance to spinal motion, particularly around neutral posture in the region of neutral zone. As the spine bends forward (flexion) the stabilizing member **10** is tensioned (see FIG. 3d) and when the spine bends backward (extension) the stabilizing member **10** is compressed (see FIG. 3e).

The resistance to displacement provided by the dynamic spine stabilizing member **10** is non-linear, being greatest in its central zone so as to correspond to the individual’s neutral zone; that is, the central zone of the stabilizing member **10** provides a high level of mechanical assistance in supporting the spine. As the individual moves beyond the neutral zone,

the increase in resistance decreases to a more moderate level. As a result, the individual encounters greater resistance to movement (or greater incremental resistance) while moving within the neutral zone.

The central zone of the dynamic spine stabilization system **11**, that is, the range of motion in which the spine stabilization system **11** provides the greatest incremental resistance to movement, may be adjustable at the time of surgery according to exemplary embodiments of the present disclosure to suit the neutral zone of each individual patient. Thus, according to exemplary embodiments of the present disclosure, the resistance to movement provided by the dynamic spine stabilizing member **10** is adjustable pre-operatively and/or intra-operatively. This adjustability helps to tailor the mechanical properties of the dynamic spine stabilizing system **11** to suit the compromised spine of the individual patient. In addition, according to exemplary embodiments of the present disclosure, the length of the dynamic spine stabilizer **10** may also (or alternatively) be adjustable intra-operatively to suit individual patient anatomy and to achieve desired spinal posture. In such exemplary embodiments, the dynamic spine stabilizing element **10** can be re-adjusted post-operatively with a surgical procedure to adjust its central zone, e.g., to accommodate a patient’s altered needs.

With reference to FIG. 4, ball joints **36**, **38** may be employed according to exemplary embodiments of the present disclosure to link or otherwise join the dynamic spine stabilizing member **10** with pedicle screws **16**, **18**. The junction of the dynamic spine stabilizing member **10** and pedicle screws **16**, **18** is free and rotationally unconstrained. Thus, three rotational degrees of freedom are provided by advantageous dynamic junctions according to the present disclosure. Alternative structural arrangements are contemplated to provide the desired rotational degrees of freedom of the disclosed dynamic joints, e.g., universal joint structures of the type disclosed in FIG. 29 and discussed herein below. The structures mounted with respect to the pedicle screw that support or accommodate motion relative to the pedicle screw, e.g., the disclosed spherical elements and universal joint mechanisms, are exemplary motion interface elements according to the present disclosure. Therefore, first of all, by providing the dynamic junctions of the present disclosure, the spine is allowed all physiological motions of bending and twisting and, second, the dynamic spine stabilizing member **10** and pedicle screws **16**, **18** are protected from potentially harmful bending and/or torsional forces, or moments. As previously stated, while ball joints are disclosed in accordance with an exemplary embodiment of the present disclosure, the present disclosure is not limited to use of one or more ball joints, and other linking structures/mechanisms may be utilized without departing from the spirit or scope of the present disclosure.

As there are ball joints **36**, **38** mechanically cooperating with each end of the stabilizing member **10** according to the exemplary embodiment of FIG. 4, bending moments are generally not transferred from the spine to the stabilizing member **10** within stabilizing system **11**. Further, it is important to recognize that the only forces associated with operation of stabilizing member **10** are the forces due to the forces of springs **30**, **32** that form part of stabilizing member **10**. These forces are solely dependent upon the tension and/or compression of the stabilizing member **10** as determined by spinal motion. In summary, the forces associated with operation of stabilizing member **10** are limited to the spring forces. Irrespective of the large loads on the spine, such as when a person carries or lifts a heavy load, the loads experienced by stabilizing member **10** are only associated with the spring forces developed within stabilizing member **10**, which are the result

of spinal motion and not the result of the spinal load. The stabilizing member **10** is, therefore, uniquely able to assist the spine without enduring the high loads of the spine, allowing a wide range of design options.

The loading of the pedicle screws **16, 18** in the presently disclosed stabilizing system **11** is also quite different from that in prior art pedicle screw fixation devices. The only load experienced by the pedicle screws **16, 18** of stabilizing system **11** is the force delivered by the stabilizing member **10** which translates into pure axial force at the ball joint-screw interface. The design and operation of the disclosed stabilizing system **11** thus greatly reduces the bending moments placed onto pedicle screws **16, 18**, as compared to prior art pedicle screw fusion systems. Due to the free motion associated with ball joints **36, 38**, the bending moment within each pedicle screw **16, 18** is theoretically zero at ball joints **36, 38**, respectively, and the potential for failure is therefore advantageously reduced. In sum, the pedicle screws **16, 18**, when used as part of the exemplary dynamic spine stabilization systems of the present disclosure, carry significantly less load and are placed under significantly less stress than typical pedicle screws.

In FIG. 2, the Moment-Rotation curve for a healthy spine is shown in configurations with an exemplary stabilizing member **10** as part of a dynamic spine stabilizing system. This curve shows the low resistance to movement encountered in the neutral zone of a healthy spine. However, when the spine is injured, this curve changes and the spine becomes unstable, as evidenced by the expansion of the neutral zone (see FIG. 1).

In accordance with exemplary embodiments of the present disclosure, people suffering from spinal injuries are best treated through devices, systems and methods that provide increased mechanical assistance in the neutral zone. As the spine moves beyond the neutral zone, the necessary mechanical assistance decreases and becomes more moderate. In particular, and with reference to FIG. 3a, an exemplary support profile contemplated through implementation of advantageously disclosed devices, systems and methods is depicted.

Three different profiles are shown in FIG. 3a. The disclosed profiles are merely exemplary and demonstrate the possible support requirements within the neutral zone. Profile **1** is exemplary of an individual requiring great assistance in the neutral zone and the central zone of the stabilizing system of the present disclosure is therefore increased, providing a high level of resistance over a great displacement; Profile **2** is exemplary of an individual where less assistance is required in the neutral zone and the central zone of the stabilizing system of the present disclosure is therefore more moderate, providing increased resistance over a more limited range of displacement; and Profile **3** is exemplary of situations where only slightly greater assistance is required in the neutral zone and the central zone of the stabilizing system of the present disclosure may therefore be decreased to provide increased resistance over even a smaller range of displacement.

As those skilled in the art will certainly appreciate, the mechanical assistance required and the range of the neutral zone will vary from individual to individual. However, the basic tenet of the present invention remains; that is, greater mechanical assistance for those individuals suffering from spinal instability is required within the individual's neutral zone. This assistance is provided in the form of greater resistance to movement provided within the neutral zone of the individual and the central zone of the dynamic spine stabilizing member **10** which advantageously forms part of a dynamic spine stabilizing system.

Exemplary dynamic spine stabilizing member **10** of the present disclosure advantageously provides mechanical assistance in accordance with the desired support profile. Further, exemplary embodiments of dynamic spine stabilizing member **10** provide for adjustability, e.g., via a concentric spring design. More specifically and with reference to exemplary embodiments of the present disclosure, spine stabilizing system **10** provides assistance to the compromised spine in the form of increased stiffness, i.e., greater incremental resistance to movement (provided by springs in accordance with a preferred embodiment) as the spine moves from the neutral posture, in any physiological direction. As mentioned above, the Force-Displacement relationship provided by exemplary stabilizing system **10** and dynamic spine stabilizing member **10** are non-linear, with greater incremental resistance around the neutral zone of the spine and central zone of the stabilizing system **11**, and decreasing incremental resistance beyond the central zone of the dynamic spine stabilizing system **11** as the individual moves beyond the neutral zone (see FIG. 3a).

The relationship of the present stabilizing system **11** to forces applied during tension and compression is further shown with reference to FIG. 3a. As discussed above, the behavior of the present stabilizing system **11** is non-linear. The Load-Displacement curve has three zones: tension, central and compression. If $K1$ and $K2$ define the stiffness values in the tension and compression zones, respectively, the advantageous stabilizing systems according to the present disclosure are designed such that high stiffness is delivered in the central zone, i.e., " $K1 + K2$ ". Depending upon the "pre-load" of stabilizing member **10**, as discussed below in greater detail, the width of the central zone and, therefore, the region of high stiffness, can be adjusted.

With reference to FIG. 4, an exemplary dynamic spine stabilizing system **11** that includes a dynamic spine stabilizing member **10** in accordance with the present disclosure is schematically depicted. Dynamic spine stabilizing system **11** includes a support assembly associated with spine stabilizing member **10** in the form of a housing **20** composed of a first housing member **22** and a second housing member **24**. The first housing member **22** and the second housing member **24** are telescopically connected via external threads formed upon the open end **26** of the first housing member **22** and internal threads formed upon the open end **28** of the second housing member **24**. In this way, the housing **20** is completed by screwing the first housing member **22** into the second housing member **24**. As such, and as will be discussed below in greater detail, the relative distance between the first housing member **22** and the second housing member **24** can be readily adjusted for the purpose of adjusting the compression of first spring **30** and second spring **32** contained within the housing **20**. Although springs are employed in accordance with a preferred embodiment of the present invention, other elastic members may be employed without departing from the spirit or scope of the present invention. A piston assembly **34** links the first spring **30** and the second spring **32** relative to first and second ball joints **36, 38**. The first and second ball joints **36, 38** are in turn shaped and designed for selective attachment to pedicle screws **16, 18**, which may extend from the respective vertebrae **12, 14** (as shown, e.g., in FIG. 2).

The first ball joint **36** is secured relative to the closed end **39** of the first housing member **22** via a threaded engagement member **40** that is shaped and dimensioned for coupling with first housing member **22**. According to an exemplary embodiment of the present disclosure, an aperture **42** is formed in the closed end **39** of the first housing member **22** and is provided with threads for engaging the threaded portion of engagement

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member 40. In this way, the first ball joint 36 substantially closes off the closed end 39 of the first housing member 22. The length of dynamic spine stabilizing system 11 may be readily adjusted by rotating the first ball joint 36 relative to first housing member 22 to adjust the extent of overlap between the first housing member 22 and the engagement member 40 of the first ball joint 36, i.e., the degree to which engagement member 40 is nested within first housing member 22. As those skilled in the art will certainly appreciate, a threaded engagement between the first housing member 22 and the engagement member 40 of the first ball joint 36 is disclosed in accordance with an exemplary embodiment of the present disclosure, although other coupling structures (e.g., welding attachment, a bayonet lock or the like) may be employed without departing from the spirit or scope of the present invention.

In an exemplary embodiment of the present disclosure, the closed end 44 of the second housing member 24 is provided with a cap 46 having an aperture 48 formed therein. As will be discussed below in greater detail, the aperture 48 is shaped and dimensioned to accommodate passage of a piston rod 50 associated with piston assembly 34 therethrough. Exemplary piston assembly 34 includes a piston rod 50; first and second springs 30, 32; and retaining rods 52. The piston rod 50 includes a stop nut 54 and an enlarged head 56 at its first end 58. The enlarged head 56 is rigidly connected to the piston rod 50 and includes guide holes 60 through which the retaining rods 52 extend during operation of the present dynamic spine stabilizing member 10. As such, the enlarged head 56 is guided along the retaining rods 52 while the second ball joint 38 moves toward and away from the first ball joint 36, i.e., in connection with relative motion between first and second ball joints 36, 38. As will be discussed below in greater detail, the enlarged head 56 interacts with the first spring 30 to create resistance as the dynamic spine stabilizing member 10 is extended and the spine is moved in flexion.

A stop nut 54 is fit over the piston rod 50 for free movement relative thereto. However, movement of the stop nut 54 toward the first ball joint 36 is prevented by the retaining rods 52 that support the stop nut 54 and prevent the stop nut 54 from moving toward the first ball joint 36. As will be discussed below in greater detail, the stop nut 54 interacts with the second spring 32 to create resistance as the dynamic spine stabilizing member 10 is compressed and the spine is moved in extension.

The second end 62 of the piston rod 50 extends from the aperture 48 at the closed end 44 of the second housing member 24, and is attached to an engagement member 64 associated with the second ball joint 38. In an exemplary embodiment of the present disclosure, the second end 62 of the piston rod 50 is coupled to the engagement member 64 of the second ball joint 38 via a threaded engagement. As those skilled in the art will certainly appreciate, a threaded engagement between the second end 62 of the piston rod 50 and the engagement member 64 of the second ball joint 38 is disclosed in accordance with an exemplary embodiment, although other coupling structures may be employed without departing from the spirit or scope of the present invention.

As briefly mentioned above, first and second springs 30, 32 are held or captured within housing 20. In particular, the first spring 30 extends between the enlarged head 56 of the piston rod 50 and the cap 46 of the second housing member 24. The second spring 32 extends between the distal end of the engagement member 64 of the second ball joint 38 and the stop nut 54 of the piston rod 50. A preloaded force applied by the first and second springs 30, 32 generally holds the piston rod in a static position within the housing 20, and the piston

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rod 50 is able to move relative to housing 20 during either extension or flexion of the spine.

In use, when the vertebrae 12, 14 are moved in flexion and the first ball joint 36 is drawn away from the second ball joint 38, i.e., there is relative motion between first and second ball joints 36, 38 such that they are moving away from each other, the piston rod 50 is pulled within the housing 24 against the force being applied by the first spring 30. In particular, the enlarged head 56 of the piston rod 50 is moved toward the closed end 44 of the second housing member 24. This movement causes compression of the first spring 30, creating resistance to the movement of the spine. With regard to the second spring 32, the second spring 32 moves with the piston rod 50 away from second ball joint 38. As the vertebrae move in flexion within the neutral zone, the height of the second spring 32 is increased, reducing the distractive force, and in effect increasing the resistance of the device to movement. Through this mechanism, as the spine moves in flexion from the initial position both spring 30 and spring 32 resist the distraction of the device directly, either by increasing the load within the spring (i.e. first spring 30) or by decreasing the load assisting the motion (i.e. second spring 32).

However, when the spine is in extension, and the second ball joint 38 is moved toward the first ball joint 36, the engagement member 64 of the second ball joint 38 moves toward the stop nut 54, which is held in place by the retaining rods 52 as the piston rod 50 moves toward the first ball joint 36. This movement causes compression of the second spring 32 held between the engagement member 64 of the second ball joint 38 and the stop nut 54, to create resistance to the movement within the dynamic spine stabilizing member 10. With regard to the first spring 30, the first spring 30 is supported between the cap 46 and the enlarged head 56, and as the vertebrae move in extension within the neutral zone, the height of the second spring 30 is increased, reducing the compressive force, and in effect increasing the resistance of the device to movement. Through this mechanism, as the spine moves in extension from the initial position both spring 32 and spring 30 resist the compression of the device directly, either by increasing the load within the spring (i.e. second spring 32) or by decreasing the load assisting the motion (i.e. first spring 30).

Based upon the use of two concentrically positioned elastic springs 30, 32 as disclosed in accordance with an exemplary embodiment of the present invention, an assistance (force) profile as shown in FIG. 2 is provided by the present dynamic spine stabilizing member 10. That is, the first and second springs 30, 32 work in conjunction to provide a large elastic force when the dynamic spine stabilizing member 10 is displaced within the central zone of the stabilizing system 11. However, once displacement between the first ball joint 36 and the second ball joint 38 extends beyond the central zone of the stabilizing system 11 and the neutral zone of the individual's spinal movement, the incremental resistance to motion is substantially reduced as the individual no longer requires the substantial assistance needed within the neutral zone. This is accomplished by setting the central zone of the device disclosed herein. The central zone of the force displacement curve is the area of the curve, which represents when both springs are acting in the device as described above. When the motion of the spine is outside the neutral zone and the correlating device elongation or compression is outside the set central zone, the spring, which is elongating, reaches its free length. Free length, as anybody skilled in the art will appreciate, is the length of a spring when no force is applied. In the advantageous, exemplary mechanism of the present disclosure, the resistance to movement of the device outside

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the central zone (where both springs are acting to resist motion) is only reliant on the resistance of one spring: either spring 30 in flexion or spring 32 in extension.

As briefly discussed above, exemplary dynamic spine stabilizing member 10 may be adjusted by rotation of the first housing member 22 relative to the second housing member 24. This movement changes the distance between the first housing member 22 and the second housing member 24 in a manner which ultimately changes the preload placed across the first and second springs 30, 32. This change in preload alters the resistance profile of the present dynamic spine stabilizing member 10 from that shown in Profile 2 of FIG. 3a to an increase in preload (see Profile 1 of FIG. 3a), which enlarges the effective range in which the first and second springs 30, 32 act in unison. This increased width of the central zone of the stabilizing member 10 correlates to higher stiffness over a larger range of motion of the spine. This effect can be reversed, as is evident in Profile 3 of FIG. 3a.

The present dynamic spine stabilizing member 10 is attached to pedicle screws 16, 18 extending from the vertebral section requiring support. During surgical attachment of the dynamic spine stabilizing member 10, the magnitude of the stabilizer's central zone can be adjusted for each individual patient according to exemplary embodiments of the present disclosure, as judged by the surgeon and/or quantified by an instability measurement device. This adjustable feature of the dynamic spine stabilizing member 10 is exemplified in the three explanatory profiles that have been generated in accordance with an exemplary embodiment of the present invention (see FIGS. 3a and 3b; note the width of the device central zones).

Pre-operatively, the first and second elastic springs 30, 32 of the dynamic spine stabilizing member 10 can be replaced by a different set of springs (in whole or in part) to accommodate a wider range of spinal instabilities. As expressed in FIG. 3b, Profile 2b demonstrates the force displacement curve generated with a stiffer set of springs when compared with the curve shown in Profile 2a of FIG. 3b.

Intra-operatively, the length of exemplary dynamic spine stabilizing member 10 may be adjustable, e.g., by turning engagement member 40 of the first ball joint 36 to lengthen the stabilizing member 10 in order to accommodate different patient anatomies and desired spinal posture. Pre-operatively, the piston rod 50 may be replaced with piston rods of differing lengths/geometries to accommodate an even wider range of anatomic variation.

The exemplary dynamic spine stabilizing member 10 disclosed herein has been tested alone for its load-displacement relationship. When applying tension, the dynamic spine stabilizing member 10 demonstrated increasing resistance up to a pre-defined displacement, followed by a reduced rate of increasing resistance until the device reached its fully elongated position. When subjected to compression, the dynamic spine stabilizing member 10 demonstrated increasing resistance up to a pre-defined displacement, followed by a reduced rate of increasing resistance until the device reached its fully compressed position. Therefore, the dynamic spine stabilizing member 10 exhibits a load-displacement curve that is non-linear with the greatest resistance to displacement offered around the neutral posture. This advantageous behavior helps to normalize the load-displacement curve of a compromised spine.

In another exemplary embodiment of the present disclosure, with reference to FIG. 5, the stabilizing member 110 may be constructed with an in-line spring arrangement. In accordance with this embodiment, the housing 120 is composed of first and second housing members 122, 124 which

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are coupled with threads allowing for adjustability. A first ball joint 136 extends from or relative to the first housing member 122. The second housing member 124 is provided with an aperture 148 through which the second end 162 of piston rod 150 extends. The second end 162 of the piston rod 150 is attached relative to the second ball joint 138. For example, the second ball joint 138 may be screwed onto the piston rod 150.

The piston rod 150 includes an enlarged head 156 at its first end 158. The first and second springs 130, 132 are respectively secured between the enlarged head 156 and the closed ends 139, 144 of the first and second housing members 122, 124. In this way, the stabilizing member 110 provides resistance to both expansion and compression using the same mechanical principles described for the previous embodiment, i.e., stabilizing member 10.

Adjustment of the resistance profile in accordance with this alternate embodiment may be achieved by rotating the first housing member 122 relative to the second housing member 124. Rotation in this way alters the central zone of high resistance provided by stabilizing member 110. As previously described, one or both springs may also be exchanged to change the slope of the force-displacement curve in two or three zones, respectively.

To explain how the exemplary stabilizing members 10, 110 assist a compromised spine (increased support in the neutral zone), reference is made to the moment-rotation curves (FIG. 6). Four curves are shown: 1. Intact, 2. Injured, 3. Stabilizer ("DSS") and, 4. Injured+Stabilizer ("DSS"). These are, respectively, the Moment-Rotation curves of the intact spine, injured spine, stabilizer alone, and stabilizer plus injured spine. Of note, the latter curve (i.e., injured spine plus stabilizing system of the present disclosure) is close to the intact curve. Thus, the stabilizer/stabilizing system of the present disclosure, which provides greater resistance to movement around the neutral posture, is well suited to compensate for the instability of the spine.

With reference to FIGS. 8 to 17, further embodiments of the advantageous stabilizing system 211 of the present disclosure (and associated force profile characteristics) are schematically depicted and described herein. This exemplary stabilizing system 211 includes first and second concentric springs 212, 214 as part of stabilizing member 210 that is positioned between first and second pedicle screws 216, 218, as generally shown in the exploded view of FIG. 8. As those skilled in the art will appreciate, the springs that are incorporated in stabilizing member 210 may take a variety of forms known to those skilled in the art, for example, machine springs, wire coil springs, wave springs, and the like, without departing from the spirit or scope of present the invention. In addition, it is contemplated that other resistance devices may be incorporated in stabilizing member 210, for example, elastomeric materials and/or elastomeric structures, Belleville washers, and the like (such alternative resistance devices being used alone or in combination with the foregoing springs), without departing from the spirit or scope of the present invention.

Stabilizing system 211 generally defines a first end 220 and a second end 222. The schematic depiction of FIG. 8 includes a pair of pedicle screws (216, 218), but it is to be understood that the "first end" and/or the "second end" may form intermediate locations, with additional pedicle screw and/or stabilizing members positioned therebeyond. Toward the first end 220, a first attachment member 224 is provided that is configured and dimensioned to receive a first ball (or spherical element) 262a to define a first ball joint 226 that accommodates relative movement between the first attachment member 224 and pedicle screw 216. Indeed, the dynamic

junction formed at ball joint **226** advantageously provides three rotational degrees of freedom. Toward the second end **222** of stabilizing system **211**, a second attachment member **228** is provided that is configured and dimensioned to receive a second ball (or spherical element) **262b** to define a second ball joint **230**. The second ball joint advantageously accommodates relative movement between the second attachment member **228** and pedicle screw **218**, i.e., defines a dynamic junction that provides three rotational degrees of freedom.

In the exemplary embodiment of FIG. **8**, ball joints **226**, **230** include a socket **232**, **234** formed integrally with the respective first and second attachment members **224**, **228** and a ball or sphere **236**, **238** positioned therein. Of course, sockets **232**, **234** may be fabricated as separate components from first and second attachment members **224**, **228** without departing from the spirit or scope of the present disclosure. In implementations wherein the sockets are fabricated separately from the attachment members, appropriate mechanisms for joining/connection such sub-assemblies may be employed, e.g., welded connections, threaded engagements, bayonet locking mechanisms or the like.

According to the exemplary embodiment of FIGS. **8-17**, the first attachment member **224** is structured for supporting the inner first spring **212** for operation in accordance with the present stabilizing system **211**. As best seen in FIGS. **16** and **28**, the first attachment member **224** includes a body member **240** having an aperture **242** extending therethrough. The inner surface of aperture **242** defines socket **232** and is shaped and dimensioned for receipt of ball (or spherical element) **236**. The assembly of the ball/spherical element is achieved by rotating the ball 90 degrees off of the normal position of the ball relative to socket **232**. At this position the ball/spherical element can slide through two opposed slots **232a** cut in the internal spherical race of the socket. In exemplary embodiments of the present disclosure, the opposed slots are substantially arcuate and extend for a distance that accommodates the height of the spherical element. Once positioned within the socket, the ball/spherical element is generally rotated relative to the socket to prevent disengagement therefrom. Indeed, once assembled onto the pedicle screw, there is no possibility of the ball/spherical element coming disassembled from the internal spherical race formed in the socket member. In exemplary embodiments of the present disclosure, aperture **242** is sized such that ball/spherical element **236** engages socket **232** at or near a plane that defines the diameter of ball/spherical element **236**. In this way, ball/spherical element **236** is centrally positioned relative to socket **232** and is not permitted to pass through socket **232**. The inner first spring **212** extends from, and in an exemplary embodiment is integrally formed with, the body member **240** of the first attachment member **224**.

The second attachment member **228** similarly includes a body member **244** having an aperture **246** extending there-through. The inner surface of the aperture **246** defines a socket **234** that is shaped and dimensioned for receipt of the ball **238**. Thus, in exemplary embodiments, socket **234** includes opposed slots to accommodate introduction of a ball/spherical element, as described above with reference to socket **232**. As with the dimensional relationship between ball **236** and socket **232**, aperture **246** is advantageously dimensioned such that ball **238** is engaged by socket **232** at or near a plane that defines the diameter of ball **238** (and ball **238** is not permitted to pass through socket **232**). The second attachment member **228** further includes a rod connector **248** with a transverse aperture or channel **250** extending therethrough. The transverse aperture or channel **250** is shaped and dimensioned for passage of spring cap rod **252** therethrough. The spring cap

rod **252** is secured within the transverse aperture **250**, e.g., via a set screw **254** extending through a threaded aperture that provides a channel from the external surface of the rod connector **248** and the transverse aperture/channel **250** within which is positioned spring cap rod **252**.

In accordance with an alternate embodiment, and with reference to FIG. **10**, set screw **254'** interacts with a wedge member **249'**. The wedge member **249'** is seated within transverse aperture/channel **250'** and is shaped and dimensioned for engaging the spring cap rod **252** as it passes through the transverse aperture/channel **250'**. More particularly, the wedge member **249'** includes an exposed arcuate surface that is shaped and dimensioned to interact with spring cap rod **252'** to substantially prevent movement of the spring cap rod relative to the second attachment member **228'** when set screw **254'** is tightened against wedge member **249'**.

With reference to FIGS. **11**, **15a** and **15b**, a further alternative structural arrangement for securing a spring cap rod relative to an attachment member according to the present disclosure is schematically depicted. The structural arrangement of FIGS. **11**, **15a** and **15b** may be particularly advantageous when it is desirable to provide flexible loading of the spring cap rod within the attachment member. The alternate embodiment of FIGS. **11**, **15a** and **15b** employs a selectively rotatable ball **249''** within transverse aperture/channel **250''** defined in attachment member **228''**. The ball **249''** includes a transverse compression slot **251''** extending therethrough. A plurality of internal grooves **253** opening into opening **255** are also formed in ball **249''** to further facilitate gripping of a spring cap rod **252''** positioned therewithin, as described in greater detail below. Of note, opening **255** formed in ball **249''** and shown in FIG. **15b** is advantageously elliptical in geometry, with a minor axis "Y" and a major axis "Z". Compression slot **251''** is substantially aligned with the minor axis "Y" and grooves **253** are deployed in an arcuate manner in facing relation to compression slot **251''**, i.e., on the opposite side of opening **255**.

In use, after an element is positioned within opening **255**, e.g., an elongated member such as a rod, a mechanism (e.g., set screw **254''**) is used to apply a force to the exterior of ball **249''**. The force is advantageously applied to ball **249''** in substantial alignment with the major axis "Z" of elliptical opening **255**. As force is applied to the outer surface of ball **249''**, the elliptical opening **255** is deformed and assumes a circular (or substantially circular) geometry. Deformation into a circular geometry is facilitated by the positioning of compression slot **251''** and grooves **253** relative to opening **255**. Indeed, the positioning of compression slot **251''** and grooves **253** accommodates preferential deformation of ball **249''** to a desired circular (or substantially circular) opening **255**. By assuming a circular/substantially circular geometry, the inner wall of ball **249''** around opening **255** engages an elongated member/rod of circular cross section around substantially the entire circumference of the elongated member/rod. By engaging the elongated member/rod around substantially the entire circumference thereof, greater security is imparted between the ball and the elongated member/rod.

Thus, the slot **251''** and grooves **253** allow the ball **249''** to be compressed and deformed to a limited degree by force imparted by the set screw **254''**, thereby locking the ball **249''** and spring cap rod **252''** in position within the transverse aperture/channel **250''**. The ball **249''** allows the spring cap rod **252''** to extend therethrough while the orientation of the ball **249''** and spring cap rod **252''** relative to the second attachment member **228''** is adjusted to a desired orientation. Stated differently, ball **249''** has three degrees of rotational freedom within aperture/channel **250''** such that the ball **249''**

can be oriented at essentially any angle to accommodate alignment with spring cap rod **252**" (or another elongated member/rod), thereby greatly enhancing the ease and flexibility of assembly associated with a spinal stabilization system. Indeed, a rod positioned within ball **249**" is generally trimmed-to-length by a clinician/surgeon once assembled with an attachment member; if trimmed very close to the exiting edge of ball **249**", the ball/rod combination will exhibit essentially 180° of rotational freedom relative to attachment member **228**". High degrees/levels of angulation, as are accommodated by the exemplary embodiments disclosed herein, are generally advantageous in clinical applications. The combination of ball **249**" with aperture/channel **250**" of attachment member **228**" may be termed a "ball-in-a-box." Once the desired orientation is achieved for the rod relative to other components of a spinal stabilization system, the set screw **254**" may be tightened and the assembly is thereby locked in position.

With further reference to FIG. **8**, the first and second attachment members **224**, **228** are adapted to be mounted upon pedicle screws **216**, **218**. Each of the pedicle screws **216**, **218** includes a proximal end **256** and a distal end **258** (inasmuch as the first and second pedicle screws **216**, **218** in the exemplary embodiment depicted herein are identical, the same numeric designations will be used in describing both pedicle screws; however, it is contemplated that pedicle screws having differing structural and/or functional features may be incorporated into stabilizing system implementations according to the present disclosure without departing from the spirit or scope hereof). The distal end **258** includes traditional threading adapted for secure attachment along the spinal column of an individual. According to exemplary embodiments of the present disclosure and with further reference to FIG. **23**, the proximal end **256** of pedicle screw **216** is provided with a collet **260** that is sized for receipt in a substantially cylindrical receiving aperture/channel **262a** formed within ball/spherical element **236**.

Collet **260** is fabricated and/or formed with an ability to expand and contract, e.g., under the control of medical practitioner(s) involved in using stabilizing system **211**. Exemplary collet **260** includes a plurality of upstanding segments **264** that are arranged in a substantially arcuate manner around a central cavity **266**, i.e., around the periphery of central cavity **266**. Adjacent upstanding segments **264** are separated by a slot or channel **265**. As shown in FIG. **23**, slot **265** may define an enlarged, substantially circular region **265a** at a base thereof. In exemplary embodiments of the present disclosure, circular region **265a** further facilitates relative movement of adjacent upstanding segments **264**.

With further reference to FIGS. **8** and **23**, exemplary collet **260** defines three (3) upstanding segments **264** that are substantially identical in geometry/dimension, although alternative numbers, spacings and/or arrangements of upstanding segments **264** may be utilized and/or employed without departing from the spirit or scope of the present disclosure. As will be explained below in greater detail, the upstanding segments **264** are adapted for movement between: (i) an expanded (or outwardly deflected) state for locking collet **260** within a receiving channel **262a**, **262b** of a ball/spherical element **236**, **238** and (ii) an unexpanded (or rest) state wherein the collet **260** may be selectively inserted or removed from a receiving channel **262a**, **262b** of a ball/spherical element **236**, **238**. Of note, the "expanded state" is generally not associated with a fixed or predetermined degree of expansion, but rather is generally defined by the level of expansion (i.e.,

outward deflection) required to achieve a desired frictional engagement between collet **260** and ball/spherical element **236**, **238**.

According to exemplary embodiments of the present disclosure, each of the receiving channels **262a**, **262b** of the respective balls/spherical elements **236**, **238** is configured and dimensioned for receiving a collet **260** associated with a pedicle screw **216**, **218** while in its unexpanded (or substantially unexpanded) state. Retention of the collet **260** may be further enhanced by the provision of a lip **268** at (or adjacent) the distal or upper end of upstanding segments **264** of collet **260**. A lip **268** is generally formed on each upstanding segment **264**, e.g., during the molding or machining of collet **260**, and generally extends around the available perimeter of collet **260**. Each of the receiving channels **262a**, **262b** generally includes first and second chamfered regions at opposite ends thereof. The chamfered regions facilitate alignment and connection of components of the disclosed stabilizing system, e.g., interaction between pedicle screws **216**, **218** and balls/spherical elements **236**, **238**. To facilitate flexibility in use of the disclosed stabilizing system, balls/spherical elements **236**, **238** are generally symmetric around or relative to a mid-plane (designated by phantom line "MP" in FIG. **23**). Accordingly, the chamfered regions at either end of receiving channels **262a**, **262b** are substantially identical in geometry and dimension.

As noted above, lips **268** are formed on the outer walls of upstanding segments **264** and are advantageously configured and dimensioned to cooperate with the chamfered regions of receiving channels **262a**, **262b**. Thus, once collet **260** is extended through a receiving channel **262a**, **262b**, the lips **268** associated with upstanding segments **264** are generally positioned in a chamfered region associated with the receiving channel **262a**, **262b**. Frictional interaction between the lips **268** and the chamfered face of the receiving channel **262a**, **262b** generally helps to maintain relative positioning of the collet **260** and the receiving channel **262a**, **262b**, e.g., both before and after expansion of the collet **260** as described herein.

According to exemplary embodiments of the present disclosure, structural features and/or elements are provided on ball/spherical element **236**, **238** and/or collet **260** to facilitate interaction with one or more tools, e.g., tools for securing a ball/spherical element **236**, **238** relative to a pedicle screw **216**, **218** and/or other components associated with stabilizing system **211**. With reference to the exemplary system of FIGS. **8** and **23**, alignment tabs or cut-outs **270**, **272** are formed in upstanding segments **264** for tool interaction. The alignment tabs/cut-outs **270**, **272** shown in FIG. **23** have a substantially L-shaped geometry, although alternative geometries may be employed to accommodate specific tool designs and/or tool interactions. In the exemplary embodiment of FIGS. **8** and **23**, a tool (not pictured) may advantageously interact with adjacent alignment tabs/cut-outs **270**, **272**, e.g., through arcuately arranged gripping extensions that are spaced, configured and dimensioned to engage/cooperate with adjacent alignment tabs/cut-outs. As noted above, balls/spherical elements **236**, **238** are generally symmetric relative to a mid-plane ("MP") and the disclosed alignment tabs/cut-outs **270**, **272** are typically formed at both ends of balls/spherical elements **236**, **238**. Indeed, the provision of alignment tabs/cut-outs **270**, **272** on both ends of balls/spherical elements **236**, **238** advantageously facilitates the mounting of a ball **236**, **238** in either orientation without sacrificing functionality/interactivity, e.g., interaction with an ancillary tool or the like. According to exemplary embodiments of the present disclosure, complementary notches **271** may be formed in balls **236**, **238** to

facilitate tool interaction. Notches 271 are generally spaced around the periphery of ball 262a, 262b, and may be brought into alignment with cut-outs 270, 272, e.g., by rotational reorientation of ball 262a, 262b relative to collet 260, by a tool (not shown) in connection with tool-related manipulation thereof. Also, there can be geometry and/or structure on the pedicle screw which is configured to interact with the cut-outs on the ball/spherical element to automatically orient and provide rotational stability to allow for counter torque, e.g., when fixing the ball/spherical element relative to the pedicle screw.

Expansion of the exemplary collet 260 associated with pedicle screw 216, 218 may be achieved by the insertion of a set screw 274 within the central aperture 266 defined within upstanding segments 264 of collet 260. In accordance with an exemplary embodiment, set screw 274 is secured within the central aperture 266 via mating threads formed along the inner surface of the central aperture 266 and the outer surface of the set screw 274. Set screw 274 generally includes an outwardly tapered portion 274a, e.g., at or adjacent the non-threaded end thereof, which is configured and dimensioned to engage upstanding segments 264 of collet 260 as screw 274 is threaded relative to pedicle screw 216, 218. Thus, as set screw 274 moves downwardly within the central aperture 266, the upstanding segments 264 are contacted by the outwardly tapered portion 274a of screw 274 and are forced/deflected outwardly. Outward deflection of upstanding segments 264 increases the effective diameter of the collet 260, increasing (or establishing) interference contact between the outer surface of collet 260 and the inner wall of receiving channel 262a, 262b. By further insertion of set screw 274, collet 260 may be brought into locking engagement with the receiving channel 262a, 262b of ball/spherical element 236, 238. As noted previously, lips 268 may be provided on the outer surface of upstanding segments 264 to, inter alia, enhance the “locking” forces imparted by collet 260.

With reference to FIGS. 24a, 24b and 24c, an alternative collet-based system for securing or mounting a ball/spherical element relative to a pedicle screw according to the present disclosure is depicted. The collet-based system of FIGS. 24a-24c is similar to the system depicted in FIG. 23. However, in the system of FIGS. 24a-24c, an internal snap ring 273 is provided that is configured to cooperate with an external ring groove 277 formed in the outer wall of upstanding segments 264 and an internal ring groove 279 formed in ball/sphere 236. Snap ring 273 defines a partial circle, with opening 273a facilitating expansion of the diameter of snap ring 273. Typically, snap ring 273 is fabricated from an appropriate metallic material, e.g., titanium or stainless steel, that provides a desired degree of elasticity. The depths of external and internal ring grooves 277, 279, respectively, are generally selected to ensure seating of snap ring 273.

In use, snap ring 273 is typically positioned in the internal groove formed in the ball/spherical element and essentially “snaps” into place with the outer groove formed in the collet, i.e., when the components reach the desired alignment. This “snap” connection between the ball/spherical element and the collet/pedicle screw allows the clinician to take appropriate steps to more permanently secure the components relative to each other (e.g., locate and position appropriate tools) without risk that the components will become misaligned. Thus, the snap ring advantageously aligns with and partially nests within both ring grooves 277, 279, thereby providing a further engagement between ball/sphere 236. As set screw 274 is screwed into place, the upstanding segments 264 deflect outward, thereby providing a greater engagement between ball/sphere 236 and pedicle screw 216. In alternative embodiment hereof, the snap ring may be initially positioned on the outer

surface of the collet (i.e., in the outer groove), in which case the snap ring “snaps” into the inner groove of the ball/spherical alignment when the desired alignment is achieved.

Of note, with a snap ring included in the disclosed assembly, the collet is no longer required to deform both inwardly and outwardly. The function of the lip on the collet may be replaced by the snap ring which separates the function of the temporary snap fit and final securement. Due to this separation of mechanical function imparted by snap ring 273, the depth of slots/channels 265 may be reduced in the exemplary embodiment of FIGS. 24a-24c relative to the embodiment of FIG. 23, without diminishing the effectiveness of secure interaction between the ball/spherical element and the collet. The potential for reducing the depth of slots/channels 265 arises because the slots/channels no longer need to allow deformation inward. Since only outward deflection of upstanding segments 264 is required to achieve the requisite securing force, the slot/channel depth may be reduced, thereby stiffening and strengthening the collet. The selection of an appropriate depth for slots/channels 265 is well within the skill of persons skilled in the art based on the present disclosure. By reducing the depth of slots/channels 265, greater strength may be imparted to collet 260.

With reference to FIGS. 25a-25c, a further alternative mechanism is depicted wherein the collet is non-deflecting, i.e., the slots/channels from the preceding embodiments are eliminated. Thus, collet 260' defines a substantially cylindrical structure, rather than a plurality of upstanding, deflectable segments that are separated by slots/channels 265, as described with reference to the preceding embodiments. The cylindrical structure imparts additional strength to collet 260', relative to the previously described slotted embodiments. As with the embodiment of FIGS. 24a-24c, an internal snap ring 273 is provided and is adapted to nest within internal and external ring grooves 277, 279 in the manner described above. Interaction between snap ring 273 and ring grooves 277, 279 provides a securing force between collet 260' and ball/sphere 236.

With particular reference to the exploded view of FIG. 25b and the cross-sectional view of FIG. 25c, set screw 274' defines an enlarged head 274a that is dimensioned to cooperate with the chamfered opening to ball/sphere 236. A tapered, circumferential bearing surface 274b is defined on the lower portion of head 274a, which is adapted to engage ball/sphere 236 as set screw 274' is screwed into collet 260'. Cooperating screw threads are generally defined on the exterior of the downwardly extending portion of set screw 274' (e.g., 6-32 thread) and on the inner surface of collet 260'. Thus, as set screw 274' is advanced into collet 260', bearing surface 274b engages a cooperating chamfered surface on ball/sphere 236. At the same time, an angled, circumferential bearing surface 261 that is defined by (or associated with) pedicle screw 216 is brought into engagement with the symmetrically defined, chamfered surface at the opposite end of ball/sphere 236. Thus, the ball/sphere 236 is effectively captured between the enlarged head of set screw 274' and bearing surface 261 is positioned adjacent the base of collet 260'.

According to the alternative embodiment of FIGS. 25a-25c, the strength of the collet is increased through elimination of the slots/channels. In addition, the greater size of the enlarged head of set screw 274' permits a larger hexagonal (or other geometrically shaped) tool engagement feature relative to the previously described embodiments. Moreover, a “tissue-friendly” surface feature 274c may be defined on the upper surface of the enlarged head to shield tissue from the space within ball/spherical element 236. However, according to the embodiment of FIGS. 25a-25c, it is not possible to

“preload” set screw **274'** within the central aperture formed within pedicle screw (as described in greater detail below) because it is not possible to pass the ball/spherical element thereover.

With reference to FIGS. **26a-26c**, a further exemplary mechanism for securing or mounting a ball/sphere relative to a pedicle screw is depicted according to the present disclosure. As with the embodiment of FIGS. **25a-25c**, a non-slotted collet is provided in association with pedicle screw. Also, as with the preceding embodiment, an angled, circumferential bearing surface **261** is positioned adjacent the base of the collet and is configured and dimensioned to engage an inner surface defined by the ball/sphere. Bearing surface **261** is defined by (or associated with) pedicle screw **216** and is positioned below the screw threads discussed below.

With particular reference to FIGS. **26b** and **26c**, ball/spherical element **236'** defines a threaded inner surface **236a** that is adapted to cooperate with an outwardly threaded surface **260a** formed on collet **260''**. The cooperating threads obviate the need for, and utility of, the snap rings discussed with reference to prior embodiments. Of note, one or more features are generally formed at the openings of ball/sphere **236'** to facilitate interaction with a tool (not pictured) for imparting rotational motion of ball/sphere **236'** relative to pedicle screw **216**. In like measure, one or more features are generally formed at (or near) the top of collet **260''** to facilitate interaction with a counter-torque tool (not pictured) to ensure that rotation of ball/sphere **236** results in the desired tightening of ball/sphere **236'** relative to collet **260''**. As ball/sphere **236'** is tightened relative to collet **260''**, the bottom portion of the ball/sphere engages bearing surface **261**, thereby providing further frictional engagement therebetween.

In use, the mounting mechanism of FIGS. **26a-26c** obviates the need for a set screw (as described in previous embodiments) and utilizes a non-slotted collet, thereby imparting additional strength to the collet structure relative to previously disclosed slotted collets. Assembly of the ball/sphere and the pedicle screw requires thread alignment and appropriate tool interaction to effect the desired rotation of the ball/sphere relative to the collet/pedicle screw.

With reference to FIG. **27**, a further alternative mounting mechanism is depicted wherein entry threads **236b** on the ball/sphere **236''** are configured to interact with cooperative threads **260x** at (or near) the base of slotted collet **260k**. A snap ring **273** is provided to supply further mounting security as the upstanding segments of the slotted collet **260k** are deflected outward, i.e., when set screw **274** is advanced downward relative to pedicle screw **216**.

According to exemplary embodiments of the disclosed mechanism, the entry threads are “left-handed” threads, thereby minimizing the potential for disengagement thereof as set screw **274** is introduced. Indeed, as the set screw is advanced, the ball/sphere is urged into a locked position due to the oppositely oriented threading thereof. Alternatively, the set screw could be provided with left-handed threads, and the entry threads could be right-handed to achieve the same result. In use, the mounting mechanism of FIG. **27** provides enhanced mounting security between the ball/sphere and the collet/pedicle screw through the combined contributions of the deflectable upstanding segments of the collet (in response to set screw introduction), the inclusion of the snap ring, and the inclusion of entry threads on the ball/sphere.

According to exemplary embodiments of the present disclosure, set screw **274** is advantageously “preloaded” within central aperture **266**, i.e., set screw **274** is partially threaded into central aperture **266** prior to commencing the clinical procedure. For purposes of the mounting mechanisms

described above, only the design of FIGS. **25a-25c** is not susceptible to a “preloaded” set screw (because of the enlarged head on set screw **274'**). An interference may be provided on the surface of set screw **274** to maintain the set screw **274** in an initial “preloaded” position, e.g., during shipment and initial clinical positioning/introduction of the pedicle screw relative to a patient. An exemplary interference according to the present disclosure involves a deformation in the helical thread, e.g., at or near a distal end thereof. The deformation may be effected by striking the formed thread in one or more locations (e.g., two opposed locations) with a rigid surface. In an exemplary embodiment, a pair of deformations or “pings” are formed in the screw thread at or near the distal end of the set screw. It is further contemplated that a desired interference may be achieved by providing a limited region of “off-pitch” threading along the length of the screw thread. Alternative structures and/or mechanisms may be employed to achieve the desired interference (which is easily overcome by the clinician when he/she advances the set screw relative to the pedicle screw), as will be readily apparent to persons skilled in the art from the present disclosure.

By “preloading” the set screw as described herein, clinical use of the disclosed system is facilitated, e.g., potential difficulties associated with aligning set screw **274** with central aperture **266** during a clinical procedure and/or the potential for misplacing/dropping and/or cross-threading the set screw in connection with clinical activities are substantially eliminated. Of note, the length of set screw **274** and/or the relative dimensions and/or positioning of the outwardly tapered region of set screw **274** may be advantageously selected so as to prevent or limit outward deflection of upstanding segments **264** in the “preloaded” configuration of set screw **274**.

In general, tightening and/or locking of a ball/spherical element relative to a pedicle screw is thus undertaken according to exemplary embodiments of the present disclosure by threading a set screw into a central aperture positioned at or near the head of the pedicle screw. The set screw may be advantageously pre-loaded into the central aperture to facilitate clinical use thereof. Threading of the set screw into the central aperture causes an outward deflection of a series of upstanding segments associated with a collet mechanism associated with the pedicle screw. To facilitate movement of the set screw relative to the pedicle screw, it is generally desirable to impart a “counter-torque” force to the pedicle screw so as to prevent/limit rotational motion of the pedicle screw as the set screw is inserted or withdrawn relative to the central aperture. Tools for providing a desired counter-torque (and for inserting/withdrawing a set screw) are known. According to exemplary embodiments of the present disclosure, cut-outs/alignment tabs may be formed or associated with the collet and cooperative notches may be formed or associated with the ball/spherical element to facilitate interaction with such tools, e.g., a tool for imparting a desired counter-torque force to the pedicle screw during set screw insertion/withdrawal.

Although the present disclosure has described a series of exemplary embodiments wherein a ball/spherical element is mounted with respect to a pedicle screw and cooperates with a socket member to support motion relative to the pedicle screw (i.e., act as a motion interface element) and provide an advantageous dynamic junction, it is to be understood that the present disclosure is not limited to dynamic junctions formed through interaction between a ball/spherical element and a socket member. For example, as shown in FIG. **29**, a pedicle screw **216** having an outwardly threaded collet **260a** may engage an inwardly threaded cavity **236a** that is mounted or jointed to a first universal joint mechanism **241** which func-

tions as a motion interface element. A rod **252** cooperates with first universal joint mechanism **241** at a first end thereof and a second universal joint mechanism **243** at an opposite end thereof. The design and operation of universal joint mechanisms are well known to persons skilled in the art and implementation thereof in connection with pedicle screw mounting structures of the type disclosed herein provide advantageous alternative dynamic junctions for use in stabilization systems/applications. Alternative dynamic junction assemblies may also be employed without departing from the spirit or scope of the present disclosure, as will be readily apparent to persons skilled in the art from the detailed description provided herein.

As those skilled in the art will certainly appreciate, efficient and reliable alignment of ball/spherical element **236**, **238** relative to collet **260** and within socket **232**, **234** is desirable. In accordance with exemplary embodiments of the present disclosure and with reference to FIGS. **12** and **14**, alignment activities are facilitated by providing clinicians with an advantageous guidewire system **275**. Exemplary guidewire system **275** includes a guidewire **276** and a tapered guide member **278** that defines an outwardly tapered guiding surface (e.g., a conical surface) that is shaped and dimensioned to facilitate positioning of a ball relative to a pedicle screw and/or socket systems, as described herein. Guidewire **276** generally defines a proximal end **280** and a distal end **282** with a central portion **284** therebetween. In exemplary embodiments of the present disclosure, the proximal and distal ends **280**, **282** of guidewire **276** are substantially similar to conventional guidewires that are used in conventional pedicle screw installations. However, the central section **284** is provided with an advantageous tapered guide member **278**, as described herein.

Tapered guide **278** generally defines a sloped outer surface and a base **279** that is substantially planar. Base **279** is generally dimensioned to have a maximum diameter that is slightly smaller than that of the diameter of receiving channel **262a**, **262b** (as measured in the non-chamfered regions). Typically, the difference in diameter between base **279** of tapered guide **278** and the central channel of receiving channel **262a**, **262b** is about 0.001" to about 0.020", thereby facilitating alignment of a ball relative to a pedicle screw while simultaneously ensuring non-obstructed passage of the ball relative to the base of the tapered guide. In exemplary embodiments of the present disclosure, the distal end **282** of guidewire **276** extends within the pedicle screw **216**, **218**, e.g., to a position short of the distal end **258** of the pedicle screw **216**, **218**. The tapered guide member **278** is then advantageously positioned on guidewire **276** such that base **279** is adjacent the proximal end **256** of the pedicle screw, e.g., adjacent or in contact with collet **260**.

In use, a pedicle screw may be introduced into a desired anatomical location. The disclosed guidewire system may then be advantageously employed to facilitate efficient and reliable positioning of a ball/sphere relative to the pedicle screw. The guidewire is generally fed into the pedicle screw such that the base of the disclosed tapered guide member is brought into close proximity and/or contact with the proximal end of the pedicle screw, e.g., the collet positioned at or near the head thereof. In percutaneous applications, however, the guidewire is generally positioned first, with the pedicle screw introduced to a desired anatomical location over the guidewire. A ball/spherical element (or alternative accessory structure) is then fed along the guidewire, i.e., the guidewire passes through the receiving channel of a ball/spherical element. The tapered guide member advantageously guides the ball into alignment with the proximal end of the pedicle

screw, e.g., into alignment with a collet positioned at the head of the pedicle screw. The ball/sphere then passes over the base of the tapered guide member into position at the head of the pedicle screw, e.g., with an advantageous collet of the present disclosure positioned within the receiving channel of the ball.

It is contemplated that the tapered guide member of the present disclosure may be formed with various shapes designed to suit specific needs and/or applications. For example, the tapered guide member may be spirally shaped and provided with additional guides for ensuring that a ball has a proper orientation/registration when seated upon the collet. Such an embodiment might be used in minimally invasive procedures, e.g., to facilitate proper alignment with a set screw of an attachment member. In addition, the tapered guide member may advantageously include structures and/or features to facilitate rotational alignment or registration of a component, e.g., a component having at least one asymmetrical characteristic, relative to a pedicle screw. Thus, for example, a spiral may be provided on the tapered guide member that ensures proper alignment/registration with feature(s) on the pedicle screw.

In addition, a guiding cone or tapered guide member may be used according to the present disclosure to guide a screwdriver and/or a counter-torque device down the guidewire, e.g., to facilitate accessing of the set screw with limited or non-existent visualization. In an additional advantageous embodiment of the present disclosure, the guidewire system may facilitate tool alignment/guidance to an off-axis location, e.g., a laterally spaced attachment member and/or rod connector, based on a known lateral/off-axis direction and distance relative to the pedicle screw in which the guidewire is positioned. Thus, a guide member may be slid along the guidewire that effects a predetermined and advantageous off-axis positioning of, for example, a tool (e.g., a screw driver) relative to the guidewire.

Further, a tapered guide member according to the present disclosure may have a star-shaped or triangular profile. In addition, the tapered guide member may be provided as a separate component, i.e., for assembly with the guidewire at a desired point in time, e.g., during installation of a stabilization system according to the present disclosure. In implementations where the tapered guide member is provided as a distinct component relative to the guidewire (as opposed to a pre-assembled guidewire system), the tapered guide member is advantageously passed over the guidewire and positioned at a desired axial position during the stabilization system installation process. Indeed, it is further contemplated that the tapered guide member may be formed and used separately from a guidewire, e.g., by placing the tapered guide member in juxtaposition with the proximal end of a pedicle screw, e.g., by mounting a tapered guide member relative to a collet that is associated with a pedicle screw.

With further reference to the biasing structures of exemplary stabilizing member **210**, a piston assembly **286** is provided that includes concentric springs **212**, **214**. The concentric springs take the form of an inner first spring **212** and an outer second spring **214**. As will be described below in greater detail, the piston assembly **286** further includes a spring cap **288** and a spring cap rod **252** which translate and/or transmit forces between piston assembly **286** and pedicle screws **216**, **218**. In as much as pedicle screws **216**, **218** are substantially integral with spinal structures of a patient, the structural arrangement described herein effectively translates and/or transmits forces to and from a patient's spine.

The inner first spring **212** generally defines a first end **290** and a second end **292**. As mentioned above, in exemplary embodiments of the present disclosure, first spring **212** is

rigidly secured to first attachment member **224**. The second end **292** of the inner first spring **212** is captured with respect to abutment surface **294** of spring cap rod **252**. The outer second spring **214** also defines a first end **296** and a second end **298**. In exemplary embodiments of the present disclosure, the first end **296** of the outer second spring **214** is captured with respect to spring cap **288** and the second end **298** of outer second spring **214** is rigidly secured to abutment surface **294** of spring cap rod **252**.

As discussed above, the respective first and second springs **212**, **214** are coupled to one or more structures associated with the exemplary stabilizing member **210**. According to exemplary embodiments hereof, one or both springs **212**, **214** may be rigidly (i.e., fixedly) coupled with respect to one or more component(s) associated with stabilizing member **210**. In accordance with a preferred embodiment of the present disclosure, the springs are welded to structures at one or both ends thereof, although those skilled in the art will appreciate that other coupling techniques (e.g., nesting and/or capturing techniques) may be used without departing from the spirit or scope of the present invention.

The springs **212**, **214** are generally positioned within a sheath **300**, e.g., a substantially cylindrical member, to prevent undesirable interaction or interference between the springs and anatomical structures in situ. Thus, sheath member **300** is advantageously substantially inert with respect to surrounding anatomical structures and fluids. In accordance with exemplary embodiments of the present disclosure, sheath **300** is fabricated (at least in part) of ePTFE (expanded polytetrafluoroethylene), UHMWPE (Ultra-High Molecular Weight Polyethylene), polycarbonate-urethane composite materials (e.g., copolymers and/or blends thereof), or combinations thereof, although those skilled in the art will appreciate that other materials may be used without departing from the spirit or scope of the present invention. Sheath **300** is generally fabricated from a material with sufficient elasticity to accommodate axial elongation/contraction of stabilizing member **110**, although structural arrangements to accommodate such axial motion, e.g., a bellows-like structure, may also be employed. It is contemplated that sheath **300** may include a surface treatment, e.g., a drug and/or medicinal agent, to facilitate or promote desired clinical results.

Abutment surface **294** of spring cap rod **252** is generally secured with respect to sheath **300** at a first end thereof, and spring cap **288** is generally secured with respect to sheath **300** at an opposite end thereof. Washers or C-clamps **302** are generally positioned at the junction between sheath **300** and the end member (i.e., spring cap **288** and abutment surface **294**) to facilitate interaction therebetween. In an exemplary embodiment of the present disclosure, spring cap **288** is further rigidly secured with respect to body member **240** of first attachment member **224**. A preferred method/system for securing second spring **214** and spring caps **288**, **294** is disclosed in a copending non-provisional patent application entitled "Spring Junction and Assembly Methods for Spinal Device," filed on Aug. 3, 2005 and assigned Ser. No. 11/19602. The entire contents of the foregoing non-provisional patent application are incorporated herein by reference.

As shown in FIGS. **8** and **9**, first and second springs **212**, **214**, spring cap **288** and spring cap rod **252** generally couple piston assembly **286** to pedicle screws **216**, **218** in a manner providing a desirable and advantageous force profile, despite the limited anatomical space available in spine applications. For example, when the spine moves in extension, pedicle screws **216**, **218** encounter forces that bias the pedicle screws toward each other. The forces experienced by pedicle screws

216, **218** are translated to forces on first and second attachment members **224**, **228**, which similarly are biased to move toward each other. The foregoing forces (that originate from spinal activity) generate a compressive force on stabilizing member **210**. In response to the compressive force experienced by stabilizing member **210**, a counterforce is generated within stabilizing member **210** through the spring force generated as spring cap rod **252** pushes and compresses outer second spring **214** between spring cap **288** and abutment surface **294** of spring cap rod **252**. An additional counterforce is generated by stabilizing member **210** as spring cap rod **252** pushes and compresses the inner first spring **212** between the body **240** of the first attachment member **224** and the abutment surface **294** of the spring cap rod **252**. As shown in FIG. **17**, the combined spring forces of first spring **212** and second spring **214** creates a substantially uniform force profile in response to spine movement in tension, while extension generates compression across the spring member(s).

When the spine moves in flexion, pedicle screws **216**, **218** are subject to forces that bias the pedicle screws away from each other. The forces experienced by pedicle screws **216**, **218** as the spine moves in flexion are translated to first and second attachment members **224**, **228**, which similarly experience a force that biases such components of stabilizing system **211** away from each other. A counterforce is generated by stabilizing member **210** in response to flexion motion of the spine. The counterforce is generated in part as a result of the spring force generated when the spring cap rod **252** pulls upon and extends outer second spring **214** between the spring cap **288** and abutment surface **294** of spring cap rod **252**. An additional counterforce is generated in response to flexion movement of the spine as spring cap rod **252** allows extension of the inner first spring **212** between the body **240** of first attachment member **224** and abutment surface **294** of spring cap rod **252**. As the force profile of FIG. **17** shows, the operation of springs **212**, **214** within stabilizing member **210** creates a force profile that advantageously decreases in intensity as overall spinal displacement increases/continues. At a certain point the inner spring reaches its free length and the resistance to motion is only in response to the increased elongation of the outer spring.

Referring to FIGS. **8** and **13-16**, and in accordance with an exemplary embodiment of the present disclosure, stabilizer system **211** is generally installed in the following manner. Pedicle screws **216**, **218** are positioned within the vertebrae using traditional techniques. The use of fluoroscopy for guidance of the pedicle screws is generally employed and strongly recommended. The pedicle screws **216**, **218** are typically placed lateral to the facets in order to ensure that there is no interference between a facet and the implanted system. The pedicle is first opened with a high-speed burr or an awl. Thereafter, a stabilizer pedicle probe may be used to create a channel for pedicle screws **216**, **218**. The pedicle screws **216**, **218** are generally self-tapping and therefore tapping of the pedicle screw channel typically is not required. The integrity of the pedicle channel wall is then typically checked and an appropriately sized pedicle screw **216**, **218** is installed by attaching the screw to a screw driver and introducing the screw lateral to the facets. The pedicle screw **216**, **218** is generally advanced until the head of the screw is in contact with the pedicle. Typically, placement of the pedicle screw **216**, **218** as low as possible is very important, especially in the L5 and S1 pedicles. The placement of the pedicle screws **216**, **218** is then generally checked with fluoroscopy, X-ray and/or other surgical navigation/viewing technique.

Once the pedicle screws **216**, **218** are properly installed, the distance between the pedicle screws **216**, **218** is generally

measured and rod 252 of stabilizing member 210 may be cut to proper dimension, as appropriate. Alternatively, rods 252 of varying length may be provided to permit a clinician to select a rod of desired length. Still further, means for adjusting the length of a rod 252 may be employed, e.g., a telescoping rod with mechanism(s) for securing the rod at one or more desired lengths (e.g., detent mechanisms at fixed intervals, set screw systems for fixing the telescoping rod members relative to each other, or the like).

In installation procedures that employ a guidewire system to guide alignment and/or installation of system components, guidewire(s) 276 are positioned within one or both of the pedicle screws 216, 218. According to exemplary embodiments of the present disclosure, a tapered guide member 278 is advantageously positioned adjacent the top of collet 260. However, as noted previously, a tapered guide member may be directly associated with the pedicle screw and/or collet to facilitate alignment and/or installation of system components (e.g., in implementations that do not employ a guidewire).

An attachment member 224, 228 (which encompasses a ball/sphere 236) may be slid down along a guidewire 276 until a tapered guide 278 is reached. Once the attachment member 224, 228 reaches the tapered guide 278, a more exact guiding function is imparted to the attachment member. Indeed, tapered guide 278 advantageously functions to guide the ball/sphere 236 associated with attachment member 224, 228 into alignment with collet 260 such that it is positioned/aligned for efficient sliding passage thereover. Thus, tapered guide 278 brings the center line of the channel formed in ball/sphere 236 into substantial alignment with the center line of collet 260 so that collet 260 can readily slide through the ball/sphere 236. Depending on the mounting mechanism associated with interaction between the collet and the ball/sphere (see FIGS. 23-27), the aligned components are then mounted with respect to each other.

Thus, in the exemplary embodiment of FIGS. 8 and 15-16, set screw 274 is advantageously tightened within collet 260 to effect outward deflection of the upstanding segments, thereby locking/securing the ball 236, 238 in position relative to the collet/pedicle screw. Of note, in the exemplary embodiment of FIGS. 8 and 15-16, set screw 274 may be advantageously preloaded relative to collet 260, thereby facilitating the mounting process as described previously. For alternative mounting mechanisms described herein, appropriate steps may be undertaken to secure the ball/sphere relative to the collet, e.g., rotational motion of ball 236, 238 relative to the collet. Of note, ball 236, 238 is adapted for freely rotational motion relative to attachment member 224, 228, thereby facilitating rotational mounting of the ball, if desired.

At this stage of assembly/installation, a first ball is secured relative to a first collet/pedicle screw. However, according to the present disclosure, a dynamic junction is nonetheless established because the attachment member is free to move, e.g., rotate, relative to the ball. Indeed, a "race" is generally defined therebetween to facilitate relative movement between the ball and attachment member. As such, realignment and/or reorientation of the attachment member is possible so as to facilitate alignment with an adjacent pedicle screw, i.e., for assembly of a dynamic stabilization level. Of particular note, even after mounting of an attachment member relative to an adjacent pedicle screw, the dynamic junction remains operative at the initial pedicle screw described herein, thereby accommodating anatomical shifts that may arise after installation of the disclosed dynamic stabilization system.

With further reference to FIGS. 15-16, rod 252 is aligned with a receiving portion of rod connector 248 that is associated with second attachment member 228. As with the first

attachment member discussed above, a dynamic junction is advantageously defined between socket 232 and ball/sphere 238 such that alignment between rod connector 248 and rod 252 is facilitated. Moreover, the functionality of the dynamic junction is unaffected by mounting of rod 252 relative to rod connector 248, i.e., rotational motion therebetween is not affected when a rod is secured/assembled according to the disclosed dynamic stabilization system. When rod 252 is properly aligned within rod connector 248, set screw 254 is tightened within transverse aperture 250 to lock rod 252 in position. The installation procedure is generally repeated on the opposite side of the vertebrae to complete a single level dynamic stabilization. Thus, at this stage in the assembly process, a dynamic stabilization is established for a single level, i.e., the level defined by the location of pedicle screws 216, 218 (and the associated counterparts on the opposite side of the vertebrae).

With reference to FIGS. 28 and 30 (and corresponding structures in FIGS. 8 and 19), additional structural and assembly details associated with an exemplary embodiment of the disclosed dynamic stabilizing member are now provided. As noted above, first attachment member 224 includes spring cap 228. As shown in FIG. 28, spring cap 228 includes a helical groove 229 on the outer periphery of the flange-like structure of spring cap 228. The width and depth of groove 229 are generally sized so as to accommodate the wire gage of a helical outer spring (e.g., second spring 214 of FIG. 8 or second spring 456 of FIG. 19). In addition, a post 231 extends from the flange-like structure of spring cap 228. Post 231 is generally centrally located on the flange-like structure and extends away from socket 232. An annular cavity 233 may be formed around post 231. According to exemplary embodiments of the present disclosure and with reference to FIG. 30, abutment surface 294 of spring cap rod 252 includes a helical groove 295 (akin to helical groove 229), post 297 (akin to post 231) and annular cavity 299 (233). An elongated member (rod) 301 extends from abutment surface 294 in a direction opposite to post 297. The foregoing structures and features facilitate assembly and operation of exemplary dynamic stabilizing members according to the present disclosure.

More particularly, according to exemplary embodiments of the present disclosure, inner first spring 212 is initially positioned within second (outer) spring 214, and is then positioned around or on post 231 and the opposed post 297 that extends from abutment surface 294. According to exemplary assemblies of the present disclosure, inner first spring 212 advantageously extends into annular cavity 233 and the opposed cavity 299 formed in abutment surface 294. In this way, inner first spring 212 is effectively captured between spring cap 288 and spring cap rod 252, and essentially floats relative to the opposing posts 231, 297. Thereafter, second spring 214 is threaded into groove 229 formed in spring cap 288 (or the opposed groove 295 formed in abutment surface 294). Ultimately, second spring 214 is typically fixed with respect thereto, e.g., by welding, and may be trimmed so as to be flush relative to an outer edge of the flange-like structure to which it is mounted. The outer second spring 214 is then extended so as to be threaded onto the opposing groove, i.e., the groove associated with abutment surface 294 or spring cap 288, e.g., by rotating abutment surface 294 or spring cap 288 relative to second spring 214, as the case may be. Once threaded into the opposing groove, the second spring 214 is typically fixed with respect thereto, e.g., by welding, and may be trimmed to establish a flush edge.

Of note, outer second spring 214 is typically shorter than inner first spring 212. Thus, as abutment surface 294 and spring cap 288 are brought toward each other (to permit

second spring 214 to be mounted on both), inner first spring 212 is placed in compression. The degree to which first spring 212 is compressed is generally dependent on the difference in length as between springs 212, 214. Thus, the preload compression of first spring 212 may be controlled and/or adjusted in part through selection of the relative lengths of springs 212, 214. In addition to the preload compression of inner spring 212, the mounting of outer spring 214 with respect to both spring cap 288 and abutment surface 294 places outer spring 214 in tension. The overall preload of a dynamic stabilizing member according to this exemplary embodiment corresponds to the equal and opposite forces experienced by springs 212, 214, i.e., the initial tension of outer spring 214 and the initial compression of inner spring 212.

According to exemplary embodiments of the present disclosure, inner spring 212 reaches its free length (i.e., non-compressed state) at or about the point at which a patient's movement exceeds the neutral zone. Beyond this point, inner spring 212 is free floating (on the opposed posts) and contributes no resistance to spinal movement. As described previously, the advantageous force profile supplied by the dynamic stabilization system of the present disclosure is achieved through utilization of inner and outer springs working synergistically. In particular, the force profiles for the springs are chosen to produce a reduction in the increase of mechanical resistance as the displacement moves beyond the neutral zone.

As briefly mentioned above, an axial spring configuration may be employed which generates the Force-Displacement curves shown with reference to FIG. 17, while allowing for a shorter distance between the first and second attachment members. As noted above, the Force-displacement curve is not exactly the same as that disclosed with reference to the embodiment of FIGS. 1 to 7. That is, the curve is substantially uniform during extension of the back and compression of the stabilizer, but the curve is substantially similar to that described with reference to FIGS. 3a and 3b when the back is in flexion and the stabilizer is elongated. The exemplary concentric spring design of the present disclosure allows a shorter distance between the first and second attachment members, eliminates the overhang on some previous embodiments, but this concentric spring orientation dictates that the extension curve be uniform or straight (i.e., no elbow). This profile characteristic results from the fact that both springs are loaded in extension, thus creating the exact same curve when both springs are loaded in the neutral zone, as compared to a situation wherein only one spring is loaded in flexion, i.e., while being elongated once outside the central zone of the device.

The advantageous dynamic stabilization systems disclosed herein may also be used in the stabilization of multiple level systems. Multiple level stabilization may be achieved through installation of a plurality stabilizing members coupled through a plurality of elongated members (e.g., rods) and a plurality of pedicle screws. For example and with reference to FIGS. 18 to 22, a multiple level, dynamic stabilization system 410 is schematically depicted. Multi-level stabilization system 410 may employ a variety of different attachment members 412, 414, 416. The different attachment member designs may be selected based on anatomical considerations, e.g., the spinal location for installation, and/or the position within the multi-level system. In other words, certain attachment member designs are better utilized at a first end or a second end, whereas other attachment member designs are suited for intermediate locations. While a specific combination of elements and/or components are disclosed in accordance with the exemplary multi-level stabilization system of FIGS.

18-22, those skilled in the art will readily understand from the present disclosure how the various attachment members and related structures/components may be employed to achieve dynamic stabilization at various spinal locations and/or in alternative deployment schemes.

Exemplary multi-level dynamic stabilization system 410 employs three distinct attachment members 412, 414, 416 dynamically linked by piston assemblies 418, 420 in the creation of a two level system. Of course, additional levels may be stabilized by extending the assembly with additional pedicle screws, collet/ball mounting mechanisms, dynamic stabilizing members, and elongated members/rods. The various attachment members are secured to the vertebrae through interaction with pedicle screws (not shown), as described above. Typically a dynamic junction is advantageously established between each pedicle screw (through cooperation with a ball/collet mechanism) and the attachment member mounted with respect thereto. The dynamic junction facilitates alignment with adjacent pedicle screw/attachment member subassemblies during installation/assembly of the multi-level dynamic stabilization system, and accommodates limited anatomical shifts/realignments post-installation.

With regard to dynamic stabilization between the first attachment member 412 and the second attachment member 414, the first attachment member 412 is structured for supporting inner first spring 428 and includes a body member 430 having an aperture 432 that extends therethrough. Body member 430 defines a socket 434 which is configured and dimensioned for receipt of ball 436, thereby establishing a first dynamic junction. According to the exemplary embodiment depicted herein, the inner first spring 428 extends from, and may be integrally formed with (or otherwise positioned with respect to), body member 430 of the first attachment member 412.

The second attachment member 414 similarly includes a body member 438 having an aperture 440 that extends therethrough. Body member 438 defines socket 442 which is configured and dimensioned for receipt of ball 444, thereby establishing a second dynamic junction. Second attachment member 414 further includes or defines a rod connector 446 with a transverse slot or channel 448 that extends therethrough. Transverse slot/channel 448 is configured and dimensioned to accommodate positioning and/or passage of stabilizer spring cap rod 450 therewithin. Spring cap rod 450 is generally secured within the transverse slot/channel 448 via a set screw 452 that extends between the external surface of rod connector 446 and the transverse slot/channel 448 formed by rod connector 446. As those skilled in the art will certainly appreciate, the transverse channel/slot may be structured in a variety of ways (e.g., as discussed above with reference to FIGS. 8-11). Second attachment member 414 is further associated with an inner first spring 454 that extends therefrom for interaction with third attachment member 416 (discussed below).

Piston assembly 418, which is positioned between first and second attachment members 412, 414, generally includes a pair of concentric springs. An inner first spring 428 and an outer second spring 456 are typically provided. As with the embodiment described above, inner first spring 428 and outer second spring 456 are secured with respect to an abutment surface 458 of spring cap rod 450 and body member 430 of first attachment member 412. Thus, first and second springs 428, 456 supply forces that act on (or with respect to) first and second attachment members 412, 414 during spinal movement, e.g., during extension and flexion of the spine. As is readily apparent from the discussion herein, the forces exerted on first and second attachment members 412, 414 are

translated to forces on the associated pedicle screws, thereby stabilizing the vertebrae to which the pedicle screws are mounted.

Referring now to the relationship between second attachment member **414** and third attachment member **416**, it is noted that the structural features of third attachment member **416** are substantially similar to those of second attachment member **414**. However, in exemplary two-level stabilization systems disclosed herein, third attachment member **416** does not have an inner or an outer spring extending therefrom. In such embodiments, the "second" level is not subject to dynamic stabilization. Piston assembly **420** positioned between second and third attachment members **414**, **416** is similar to the previously described piston assemblies. Generally, piston assembly **420** includes an inner first spring **454** that extends from second attachment member **414** and spring cap rod **464** extends from third attachment member **416**.

As mentioned above, first, second and third attachment members **412**, **414**, **416** may have particular utility at particular anatomical locations. For example, it is contemplated that first attachment member **412** could be most useful at position S1 and below position L5, whereas second and third attachment members **414**, **416** may be advantageously employed at L5 and above. Alternative implementations of the foregoing attachment members may be undertaken based on particular clinical needs and/or judgments.

Of note, single or multi-level dynamic spine stabilization systems/implementations according to the present disclosure permit one or more adjustments to be made (e.g., in situ and/or prior to clinical installation). For example, adjustments as to the magnitude and/or displacement-response characteristics of the forces applied by the stabilization system may be implemented, e.g., by substituting springs within one or more of the stabilizing members and/or adjusting the first/second housings, as described with reference to FIG. **8**. The adjustments may be made prior to initiating a clinical procedure, e.g., based on an evaluation of a particular patient, or after a clinical procedure, e.g., based on post-surgical experiences of a patient.

According to further exemplary embodiments of the present disclosure, multi-level spinal stabilizations may be undertaken wherein the same or differing stabilization modalities may be employed at each of the individual levels. Thus, for example, a dynamic stabilizing member according to the present disclosure may be employed at a first stabilization level, a non-dynamic stabilizing member (e.g., a rigid structure/assembly such as a rigid rod or plate connection) at a second stabilization level, and a dynamic or non-dynamic stabilizing element at a third stabilization level. The advantageous flexibility and versatility of the disclosed systems/designs for mounting relative to a pedicle screw enhance the ability to vary the stabilization modalities from level-to-level according to the present disclosure. For example, upwardly extending collets disclosed herein readily accommodate cooperative mounting with respect to both dynamic and non-dynamic stabilizing members/elements. Indeed, it is contemplated according to the present disclosure that decisions as to stabilization modalities may be made at the time of surgery, e.g., based on clinical observations and/or limitations. Moreover, it is contemplated that dynamic and non-dynamic modalities may be interchanged at a point in time post-surgery. In such applications, a first stabilizing member (whether dynamic or non-dynamic) may be disengaged from a clinically installed stabilization system, and a second stabilizing member that offers a different modality may be installed in its place. Thus, systems according to the present disclosure encompass multi-level stabilizations that include at least one

level that includes a dynamic stabilizing member and at least one level that includes a non-dynamic stabilizing element.

A kit may be advantageously provided that contains the components that may be necessary to perform clinical procedures according to the present disclosure, i.e., spine stabilization procedures. The kit contents are typically sterilized, as is known in the art, and may include appropriate labeling/indicia to facilitate use thereof. Typical kit contents include: (i) two or more attachment members (wherein one of the attachment members may include an extension member that incorporates a stabilizing member), (ii) two or more balls/spheres, and (iii) two or more pedicle screws. Alternative kits according to the present disclosure may include one or more of the following additional items: (iv) a variety or assortment of replacement springs for potential use in the dynamic stabilizing members of the present disclosure, (v) one or more tools for use in the dynamic stabilization procedures of the present disclosure (e.g., a screw driver, counter-torque device, measurement tools, tools for placement of the pedicle screws, etc.), (vi) one or more guidewires, (vii) one or more tapered guides or cones, and/or (viii) one or more set screws. The enclosures for the foregoing kits are typically configured and dimensioned to accommodate the foregoing components, and are fabricated from materials that accommodate sterilization, as are known in the art. A single kit may be broken into multiple enclosures, without departing from the spirit or scope of the present disclosure.

For exemplary embodiments of the present disclosure wherein springs are utilized in fabricating the disclosed dynamic stabilizing members, spring selection is generally guided by the need or desire to deliver a particular force profile or force profile curve, as described above. Generally, spring selection is governed by basic physical laws that predict the force produced by a particular spring design/material. However, the particularly advantageous dynamic spinal stabilization achieved according to the present disclosure (as described above and schematically depicted in FIGS. **3a**, **3b** and **17**) require a recognition of the conditions and stimuli to be encountered in a spinal environment.

A first design criterion is the fact that the dynamic stabilizing member must function both in compression and tension. Second, the higher stiffness (K_1+K_2) provided by a disclosed dynamic stabilizing member in the central zone is generally achieved through the presence of a spring preload. Both springs are made to work together when the preload is present. As the dynamic stabilizing member is either tensioned or compressed, the responsive force increases in one spring and decreases in the other. When the decreasing force reaches a zero value, the spring corresponding to this force no longer contributes to the stabilizing functionality. An engineering analysis, including the diagrams shown in FIGS. **7a** and **7b**, is presented below. This analysis specifically relates to the exemplary embodiment disclosed in FIG. **5**, although those skilled in the art will appreciate the way in which the analysis applies with equal force to all embodiments disclosed herein.

F_0 is the preload within the dynamic stabilizing member, introduced by shortening the body length of the housing as discussed above.

K_1 and K_2 are stiffness coefficients of the compression springs, active during tensioning and compression of the dynamic stabilizing member, respectively.

F and D are respectively the force and displacement of the disc of the dynamic stabilizing member with respect to the body of the dynamic stabilizing member.

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The sum of forces must equal zero. Therefore,

$$F+(F_0-D\times K_2)-(F_0+D\times K_1)=0, \text{ and}$$

$$F=D\times(K_1+K_2).$$

With regard to the central zone (CZ) width (see FIG. 3a):

On Tension side CZ_T is:

$$CZ_T=F_0/K_2.$$

On Compression side CZ_c is:

$$CZ_c=F_0/K_1.$$

While the foregoing analysis is useful in understanding the physical properties and forces associated with operation of the disclosed dynamic stabilizing member, the present disclosure is not limited to any theoretical or quantitative characterization of spring design or function. Rather, desired force profiles/force profile curves may be achieved through quantitative analysis, empirical study, or combinations thereof. In addition, as those skilled in the art will certainly appreciate, the concepts underlying the dynamic stabilization systems and associated components/assemblies may be applied to other clinical needs and/or medical/surgical procedures. As such, the disclosed devices, systems and methods may be utilized beyond spinal treatments without departing from the spirit or scope of the present invention.

Having described exemplary embodiments of the present disclosure, it is specifically noted that the present invention embodies a series of advantageous features and functions having particular utility in spinal stabilization devices/systems and associated methods, including the following:

Devices, systems and methods that provide a dynamic junction between at least one pedicle screw and at least one elongated member (or multiple elongated members), e.g., rod(s), that engage and/or otherwise cooperate with the pedicle screw. In exemplary embodiments of the present disclosure, the dynamic junction is provided through interaction between a collet/ball mechanism and a socket that is associated with an attachment member. The dynamic junction facilitates assembly of a spinal stabilization system and permits the pedicle screw/elongated member to accommodate limited degrees of anatomical realignment/reorientation post-installation.

Devices, systems and methods that provide or incorporate ball assembly mechanisms that facilitate assembly/installation of a ball/sphere relative to a pedicle screw and provide advantageous functional attributes as part of a spinal stabilization system. Exemplary mechanisms include advantageous collet-based mechanisms (e.g., slotted and non-slotted collets), cooperatively threaded mechanisms (e.g., an externally threaded collet cooperating with an internally threaded ball/sphere), mechanisms that apply bearing forces against the ball/sphere (e.g., a circumferential bearing surface formed on a set screw having an enlarged head), and/or mechanisms that include a snap ring or analogous structure. The disclosed mechanisms permit reliable mounting of a ball/sphere relative to a pedicle screw.

Devices, systems and methods that provide dynamic spine stabilization systems/implementations over a single level and/or multiple levels, including single and multi-level systems that permit one or more adjustments to be made (e.g., in situ and/or prior to clinical installation), e.g., adjustments as to the magnitude and/or displacement-response characteristics of the forces applied by the stabilization system.

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Devices, systems and methods that provide multi-level dynamic stabilization systems that include different stabilization modalities at different levels, e.g., at least one level including a dynamic stabilizing member and at least one level including a non-dynamic stabilizing member. According to exemplary embodiments of mixed multi-level stabilization systems, the dynamic and non-dynamic stabilizing elements are mounted with respect to common, i.e., identical, pedicle screws as disclosed herein.

Devices, systems and methods that provide or utilize advantageous installation accessories (e.g., cone structures) for facilitating placement and/or installation of spine stabilization system components, such accessories being particularly adapted for use with a conventional guidewires to facilitate alignment/positioning of system components relative to the pedicle screw.

Devices, systems and methods that provide or utilize dynamic spring stabilization components that include a cover and/or sheath structure that provides advantageous protection to inner force-imparting component(s) while exhibiting clinically acceptable interaction with surrounding anatomical fluids and/or structures, e.g., a cover and/or sheath structure that is fabricated (in whole or in part) from ePTFE, UHMWPE and/or alternative polymeric materials such as polycarbonate-polyurethane copolymers and/or blends.

Devices, systems and methods that provide advantageous dynamic spine stabilization connection systems that facilitate substantially rigid attachment of an elongated member (e.g., a rod) relative to the pedicle screw while simultaneously facilitating movement relative to adjacent structures (e.g., an adjacent pedicle screw) to permit easy and efficacious intra-operative system placement;

Devices, systems and methods that provide an advantageous "pre-load" arrangement for a securing structure (e.g., a set screw) that may be used in situ to mount a ball joint relative to a pedicle screw, thereby minimizing the potential for clinical difficulties associated with location and/or alignment of such securing structure(s).

Devices, systems and methods that embody or utilize advantageous kits that include an enclosure and necessary components for implementing dynamic spine stabilization in the manner described herein, such enclosure/components being supplied in a clinically acceptable form (e.g., sterilized for clinical use).

Moreover, each of the embodiments disclosed hereinabove could be advantageously modified to include travel-limiting structure, e.g., an internal cable, as will now be discussed with reference to additional exemplary embodiments of the present disclosure shown in FIGS. 31-35. Elements illustrated in FIGS. 31-35 which correspond substantially to the elements described hereinabove with reference to FIGS. 8, 9, 19, 28, and 30 have been designated by corresponding reference numerals increased by an increment of one thousand. The embodiments of the present disclosure shown in and described with reference to FIGS. 31-35 operate and are constructed in manners consistent with the foregoing description of the embodiments shown in FIGS. 8, 9, 19, 28, and 30, unless stated otherwise.

Referring to FIGS. 31-33, a stabilizing system 1304 that is similar in most respects to the stabilizing system 211 described hereinabove with reference to FIGS. 8, 9, 19, 28, and 30, with differences at least as described hereinbelow, is shown in relevant part. The stabilizing system 1304 includes a stabilizing member 1306 that is similar in most respects to the stabilizing member 210 described hereinabove with

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respect to FIGS. 8, 9, 19, 28, and 30. This exemplary stabilizing member 1306 includes inner and outer concentric springs 1212, 1214 and is positioned between two adjacent pedicle screws (not shown).

Toward an end 1220 of the stabilizing system 1304, an attachment member 1224 is provided. Toward an end 1222 of the stabilizing system 1304 opposite the end 1220 thereof, a rod 1252 is provided. The stabilizing member 1306 further includes a spring cap 1308 and a spring cap 1310. The spring cap 1308 is similar in most respects to the spring cap 228 described hereinabove with reference to FIGS. 8, 9, 19, and 28, with differences at least as discussed hereinbelow. The spring cap 1310 is similar in most respects to the abutment surface 294 described hereinabove with reference to FIGS. 8, 9, 19, and 30, with differences at least as discussed hereinbelow. The rod 1252 is attached to the spring cap 1310 in the same or a substantially similar manner in which the rods 252 (FIGS. 8 and 9) and 301 (FIG. 30) are attached to the abutment surface 294, except at least in that the rod 1252 is positioned off-center or off-axis with respect to the central axis of the spring cap 1310.

Referring now to FIGS. 31-34, spring cap 1308 includes an interior end 1312, an exterior end 1314 opposite the interior end 1312, a post 1231 formed in the interior end 1312, a pocket 1316 formed in the exterior end 1314 and within the post 1231, and an aperture or channel 1318 formed at the bottom of the pocket 1316 that passes through the post 1231 and between the interior and exterior ends 1312, 1314. Surrounding the aperture/channel 1318 at the bottom of the pocket 1316 is an annular lip 1320. The structure and function of the spring cap 1308 will be discussed in greater detail hereinafter.

The spring cap 1310 includes an interior end 1322, an exterior end 1324 opposite the interior end 1322, a post 1297 formed in the interior end 1322, a pocket 1326 formed in the exterior end 1324 and within the post 1297, an aperture or channel 1328 formed at the bottom of the pocket 1326 that passes through the post 1297 and between the interior and exterior ends 1322, 1324, an annular lip 1330 surrounding the aperture/channel 1328 at the bottom of the pocket 1326, and a sleeve insert 1332 occupying the pocket 1326 to a depth of the annular lip 1330. The outside diameter of the sleeve insert 1332 is complementary to an inside diameter of the pocket 1326 so as to limit transverse motion of the sleeve insert 1332 relative to the pocket 1326, and such that the sleeve insert 1332 is securely retained within the pocket 1326 without risk of dislodgement during medical testing or in situ use. The sleeve insert 1332 also includes an annular lip 1334 coinciding in its axial position and orientation with the annular lip 1330. The structure and function of the spring cap 1310 will be described in greater detail hereinafter.

The stabilizing member 1306 further includes a travel-limiting structure 1336 configured, dimensioned, and employed to place a positive limit on the degree to which the outer spring 1214 can extend in length and/or bend laterally, from an initial position, e.g., the starting configuration shown in FIG. 34. The travel-limiting structure 1336 includes a length 1338 of cable (e.g., metallic wire-rope cable), a termination block 1340 at one end 1342 of the cable length 1338, and a termination block 1344 at another end 1346 of the cable length 1338. The exemplary termination block 1340, which is lodged in the pocket 1316 of the spring cap 1308, has a stepped design that includes a cylindrical collar 1348 having an outer diameter that is complementary to an inner diameter of the aperture 1318 of the spring cap 1308, and a shoulder 1350 having an outer diameter that is complementary to an inner diameter of the pocket 1316. The termination block

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1344, which is lodged in, and immovably affixed relative to the sleeve insert 1332 of the spring cap 1310, includes a cylindrical collar 1352 having an outer diameter that is complementary to an inner diameter of the sleeve insert 1332.

The annular lip 1330 limits the cylindrical collar 1352 to a particular depth of insertion within the pocket 1326 of the spring cap 1310. An adhesive and/or a press-fit insertion scheme and/or any other suitable joining means (e.g., such as welding) ensures that the cylindrical collar 1352 remains immovably affixed within the sleeve insert 1332.

Referring now to FIGS. 34 and 35, in operation, the travel-limiting structure 1336 allows the spring caps 1308, 1310 of the stabilizing member 1306 to separate from each other up to a specific, predetermined distance between the posts 1231, 1297, i.e., only a predetermined relative travel therebetween is permitted. More particularly, the spring caps 1308, 1310, separated by an exemplary distance D1 of about 0.50 inches when the stabilizing member 1306 is undisturbed by external forces (see FIG. 34), are permitted additional separation up to and including a distance D2 of about 0.110 inches between the spring caps 1308, 1310 when the stabilizing member 1306 is acted upon by forces tending to expand or extend the outer spring 1214 (see FIG. 35). As the separation distance between the spring caps 1308, 1310 increases from D1 to D2, the cable length 1338 is gradually pulled through the aperture/channel 1318 (FIG. 34) of the spring cap 1308 by virtue of the termination block 1344 being fixed with respect to the sleeve insert 1332 at a maximum depth within the pocket 1326 (FIG. 34). The shoulder 1350 of the termination block 1340 travels deeper into the pocket 1316 of the spring cap 1308, typically remaining in a substantially axially-aligned orientation with respect thereto by virtue of its complementary outside diameter. Thus, smooth sliding is promoted regardless of the effective angle of the applied pulling force, and the risk of 'kinking' is substantially reduced and/or effectively eliminated.

As the separation distance between the spring caps 1308, 1310 approaches D2, the cylindrical collar 1348 of the termination block 1340 enters the aperture 1318 (FIG. 34) at the bottom of the pocket 1316. The aperture 1318 (FIG. 34) is substantially cylindrical in shape, and receives the cylindrical collar 1348 in such a way as to further limit a degree of transverse shifting and/or transverse rotation between the termination block 1340 and the pocket 1316, thereby improving axial alignment in preparation for placing the cable length 1338 in different degrees of tension between the termination blocks 1340, 1344. Concurrent with the shoulder 1350 bottoming out on and/or meeting the annular lip 1320, the separation distance between the spring caps 1308, 1310 reaches its maximum dimension D2. At this point, the termination blocks 1340, 1344 (which are affixed to the cable length 1338) and the cable length 1338 itself (which is substantially axially inextensible) cooperate in acting upon the spring caps 1308, 1310 so as to interpose a physical restraint that prevents any further axial separation therebetween. The travel-limiting functionality described herein is advantageously achieved whether the separation therebetween is accompanied by simple axial extension of the outer spring 1214, as shown in FIG. 5, lateral bending of the outer spring 1214 (not separately shown), torsional twisting of the outer spring 1214 (not separately shown), and/or a combination of two or more of the above (not separately shown). To the extent the external forces acting on the stabilization member 1306 resulting in the extension/bending/twisting of the outer spring 1214 are relaxed, the externally-induced tension in the cable length 1338 is released, and residual stiffness of the cable length 1338 tends to push the termination block 1340 outward of the pocket 1316.

The stabilizing member **1306** associated with the exemplary stabilizing system **1304** described hereinabove with reference to FIGS. **31-35** provides numerous advantages. Depending on an overall length of the cable length **1338** between the termination blocks **1340**, **1344**, the stabilizing member **1306** can be employed to limit a linear and/or angular distance between the spring caps **1308**, **1310** to any desired dimension, depending on any number of factors. Such factors may include, but are not necessarily limited to: 1) the particular physical characteristics and/or spinal support needs of the surgical patient, 2) a desire to limit an overall tensile force within the outside spring **1214** to a particular level (e.g., for purposes of meeting related durability/reliability standards), 3) a desire to induce and/or force incrementally greater involvement or contribution of adjacent intervertebral segments, and/or of other adjacent stabilization members (not shown), in the manifestation of particular instances or different types of spinal movement (e.g., in spinal flexion, extension, twist, etc.), 4) a desire to permit a small degree of intervertebral flexibility in the spine of a surgical patient whose condition would otherwise call for the employment of a spinal fusion technique. The predetermined travel distance accommodated by the travel-limiting assembly described herein may be adjustable, e.g., by allowing a repositioning of one or more termination blocks relative to the travel-limiting structure (e.g., using a set screw-based junction therebetween).

Also, the travel-limiting structure **1336** is generally substantially entirely disposed within the peripheral outlines of the inner and outer springs **1212**, **1214** and the longitudinal outlines of the spring caps **1308**, **1310**, thereby adding nothing to the overall spatial outline of the stabilizing member **1306**, thereby overcoming potential spatial compatibility concerns with respect to existing uses of such devices. Further, the travel-limiting structure **1336** is generally sufficiently flexible so as to place essentially no unnecessary limits on the type of elastic response of the outer spring **1214** associated with the desired D2 interval between the spring caps **1308**, **1310**. More particularly, such flexibility is a function of many different features of the travel-limiting structure, including but not limited to: 1) the inherent flexibility of the cable length **1338** allowing twisting and/or bending as necessary between periods at which the spring cap-spring cap distance is at its maximum, 2) the tendency of the termination block **1340** to remain axially aligned with the pocket **1316** regardless of the minor variations in the direction of the pulling force relative to the axis of the pocket **1316**, and 3) the salutary ability of the termination block **1340** to rotate axially within the pocket **1316** as needed to relieve and/or prevent the accumulation of torsional stress (e.g., based on the complementary cylindrical designs of the termination block **1340** and the pocket **1316** permitting such relative motion). Many other advantages are also provided.

The stabilizing member **1306** associated with the stabilizing system **1304** described hereinabove with reference to FIGS. **31-35** can be the subject of numerous modifications and variations while still exhibiting most or all of the above-discussed advantages. For example, rather than consisting of one limiting structure **1336**, in accordance with some embodiments of the present disclosure the stabilizing member **1306** includes two or more similar limiting structures (e.g., off-axis limiting structures), in which case such limiting structures need not necessarily be axially-aligned with the spring caps **1308**, **1310**, and need not necessarily be of the same length or (e.g., as may be considered equivalent in some instances) be disposed between annular lip structures of similar depths within the spring caps **1308**, **1310**. In some such

embodiments, the limiting structures used have the effect of limiting an overall separation of the spring caps **1308**, **1310** to different extents depending on the type of spinal motion (e.g., flexion, extension, twist) being supported. The cable length **1338** need not necessarily be comprised of metallic wire-rope cabling, but can include other materials and/or material configurations, such as flexible and strong nylon line, bundles of wires not necessarily in a wire-rope configuration, etc. Moreover, the cable length **1338** need not necessarily be substantially inelastic, but may be configured to permit at least some extension prior to reaching a maximum length. Alternatively, the cable length **1338**, rather than being strictly limiting as to the ultimate distance it permits between the spring caps **1308**, **1310**, can instead be configured so as to yield at a certain level of axially-directed force in certain extreme circumstances (e.g., if necessary in order to limit a possibility of damage being done to the bone tissue of related adjacent vertebrae by pedicle screws being subjected to undue restraint forces). The termination blocks **1340**, **1344** need not necessarily have cylindrical and/or circular transverse configurations, but can instead have other transverse shapes, such as square, rectangular, oblong, curved, irregular, etc., as desired and/or as necessary in certain applications. In another example of a possible modification, the elongate element of the limiting structure currently embodied by a length of wire-rope cable is replaced by a substantially stiff, inflexible bar or pin, and the termination blocks are modified so as to permit them to rotate in one or more planes relative to the structural members in which they are mounted (e.g., via global joints), thereby accommodating both axial extension of the outer spring as well as lateral bending thereof. Many other modifications and/or variations are possible.

Although the present disclosure has been disclosed with reference to exemplary embodiments and implementations thereof, those skilled in the art will appreciate that the present disclosure is susceptible to various modifications, refinements and/or implementations without departing from the spirit or scope of the present invention. In fact, it is contemplated the disclosed connection structure may be employed in a variety of environments and clinical settings without departing from the spirit or scope of the present invention. Accordingly, while exemplary embodiments of the present disclosure have been shown and described, it will be understood that there is no intent to limit the invention by such disclosure, but rather, the present invention is intended to cover and encompass all modifications and alternate constructions falling within the spirit and scope hereof.

The invention claimed is:

1. A stabilization member associated with a Spinal stabilization system, said stabilization member comprising:
 - (a) a first structural member that is configured and dimensioned to be mounted with respect to a pedicle screw, said first structural member including a post that defines (i) an interior pocket, and (ii) an aperture in communication with said interior pocket, said aperture having a reduced inner diameter relative to the inner diameter of the interior pocket;
 - (b) a second structural member in Spaced relation with respect to said first structural member and adapted for relative movement with respect to said first structural member;
 - (c) a resilient element disposed between and mounted with respect to said first and second structural members, said resilient element defining a first length that lengthens in response to relative movement between said first and second structural members, said resilient element defining a region that is positioned around said post of said

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first structural member such that at least a portion of said lengthening of said resilient element responsive to relative movement between said first and second structural members occurs in the region of said resilient element positioned around said post; and

- (d) a travel-limiting structure disposed between and mounted with respect to said first and second structural members, said travel-limiting structure being configured and dimensioned to define a maximum distance by which said first and second structural members may be separated and including a termination element that is sized to travel within said interior pocket but so as not to pass through said aperture of said post;

wherein said travel-limiting structure is movably mounted with respect to said first structural member and fixedly and non-translatably mounted with respect to said second structural member.

2. A stabilization member according to claim **1**, wherein, when said first and second structural members are separated by said maximum separation distance, said first and second structural members axially engage opposite ends of said travel-limiting structure.

3. A stabilization member according to claim **1**, wherein said travel-limiting structure extends through and is axially translatable with respect to another aperture defined by the second structural member, and said travel-limiting structure further includes another termination disposed at an opposite end of said travel-limiting structure and lodged within another pocket, said another pocket being defined by said second structural member and associated with said another aperture.

4. A stabilization member according to claim **3**, wherein said second structural member includes a sleeve insert lodged within said another pocket to a depth of a lip formed therein.

5. A stabilization member according to claim **4**, wherein said sleeve insert is axially aligned with said another pocket.

6. A stabilization member according to claim **1**, wherein said first structural member includes a lip formed at a bottom of said pocket adjacent said aperture.

7. A stabilization member according to claim **6**, wherein said termination further includes a shoulder disposed within said pocket that is adapted to axially translate with respect thereto to a depth of said lip.

8. A stabilization member according to claim **1**, wherein said travel-limiting structure is substantially axially inextensible.

9. A stabilization member according to claim **8**, wherein said travel-limiting structure is of a substantially fixed axial length.

10. A stabilization member according to claim **1**, wherein said travel-limiting structure comprises a metallic wire-rope.

11. A stabilization member according to claim **1**, wherein said travel-limiting structure is adjustable.

12. In combination:

- (a) a first structural member having a first side and second side opposite said first side, said first structural member including a post that defines (i) an interior pocket, and (ii) an aperture in communication with said interior pocket, said aperture having a reduced inner diameter relative to the inner diameter of the interior pocket;

(b) a second structural member having a first side and a second side opposite said first side;

(c) at least one spring disposed between and mounted with respect to said first side of said first structural element and said first side of said second structural element, said at least one spring defining a first length that lengthens in response to relative movement between said first and

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second structural members, said at least one spring defining a region that is positioned around said post of said first structural member such that at least a portion, of said lengthening of said at least one spring responsive to relative movement between said first and second structural members occurs in the region of said at least one spring positioned around said post;

- (d) a travel-limiting structure for limiting a distance of relative travel between said first and second structural elements and including a termination element that is sized to travel within said interior pocket but so as not to pass through said aperture of said post; and

(e) a pair of pedicle screws in spaced relation, wherein said first and second structural members are positioned between said pair of pedicle screws;

wherein said travel-limiting structure is movably mounted with respect to said first structural member and fixedly and non-translatably mounted with respect to said second structural member.

13. A combination according to claim **12**, wherein said travel-limiting structure is disposed between said first side of said first structural element and said first side of said second structural element and further includes another end opposite said end, said termination at said end of said travel-limiting structure is axially movably mounted to said second side of said first structural element, and said travel-limiting structure further includes another termination at said another end of said travel-limiting structure, said another termination being mounted to said second side of said second structural element.

14. A combination according to claim **12**, further comprising a first pedicle screw and a second pedicle screw, and wherein at least one of said first and second structural members is mounted with respect to said first pedicle screw.

15. A combination according to claim **12**, wherein said travel-limiting structure is positioned within a coil defined by said at least one spring.

16. A stabilization member according to claim **1**, wherein said travel-limiting structure is configured to permit at least some axial extension prior to reaching said maximum length.

17. A stabilization member according to claim **1**, wherein said travel-limiting structure includes a cable length, including wherein said cable length is not strictly limiting as to the ultimate distance said cable length permits between the first and second structural members, and further including wherein said cable length is configured so as to yield at a certain level of axially-directed force in order to limit a possibility of damage being done to the bone tissue of associated adjacent vertebrae by associated pedicle screws being subjected to undue restraint forces.

18. In combination:

- (a) a stabilization member associated with a spinal stabilization system, said stabilization member including: (i) a first structural member that is configured and dimensioned to be mounted with respect to a pedicle screw; (ii) a second structural member in spaced relation with respect to said first structural member and adapted for relative movement with respect to said first structural member; (iii) a resilient element disposed between and mounted with respect to said first and second structural members; and (iv) a travel-limiting structure disposed between and mounted with respect to said first and second structural members,

(b) a first pedicle screw; and

(c) a second pedicle screw in spaced relation relative to the first pedicle screw,

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wherein said first structural member is mounted with respect to said first pedicle screw and said second structural member is mounted with respect to said second pedicle screw; and

wherein said travel-limiting structure (i) is movably 5 mounted with respect to said first structural member; (ii) is fixedly and non-translatably mounted with respect to said second structural member; and (iii) defines a maximum distance by which said first and second structural members may be separated,

wherein said first structural member of said stabilization member includes a mounting structure for movably mounting the travel-limiting structure relative to the first structural member, said mounting structure including: 10 (i) an interior pocket, and (ii) an aperture in communication with said interior pocket, said aperture having a

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reduced inner diameter relative to the inner diameter of the interior pocket; and wherein said travel-limiting structure includes a termination element that is sized to travel within said interior pocket but so as not to pass through said aperture of said post.

19. A combination according to claim **18**, wherein said travel-limiting structure of said stabilization member is substantially axially inextensible.

20. A combination according to claim **18**, wherein said travel-limiting structure of said stabilization member comprises a metallic wire-rope.

21. A combination according to claim **18**, wherein said travel-limiting structure of said stabilization member is adjustable.

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